

Project 4430 - none

DEPARTMENT OF HEALTH

Chapter 221 Virginia's Rules and Regulations Governing Cooperative Agreements

CHAPTER 221

VIRGINIA'S RULES AND REGULATIONS GOVERNING COOPERATIVE AGREEMENTS

12VAC5-221-10. Purpose

In order to address the unique healthcare challenges that exist in the Southwest Virginia community, the General Assembly has authorized the Commissioner to approve or reject applications for Cooperative Agreements following receipt of a recommendation by the Authority. The Commissioner is authorized to issue Letters Authorizing Cooperative Agreements as recommended by the Authority that he determines, by a preponderance of the evidence, will result in benefitsare beneficial to citizens served by the Authority that outweigh the disadvantages attributable to a reduction in competition, and is responsible for to actively supervising the Parties that receive asupervise the Letter Authorizing Cooperative Agreement to ensure compliance with the provisions that have been approved. To the extent asuch Letters Authorizing Cooperative Agreement, approved under this section, or the planning and negotiations that precede such Letters, might be anticompetitive within the meaning and violateintent 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, and to invest in the Commissioner the authority to approve Letters Authorizing Cooperative Agreements recommended by the Authority and the duty to actively supervise a Party that receives a Letter Authorizing a Cooperative Agreementof active supervision to ensure compliance with the provisions of the Letter Authorizing Cooperative Agreement that have been approved. Such intent is within the public policy of the Commonwealth to facilitate the provision of quality and, cost-efficient medical care to citizens in Participating Localities. rural patients.

12VAC5-221-20. Definitions.

"Applicant" means a partythe parties to a Cooperative Agreement who submitssubmit 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 entities that desire to apply for a Letter Authorizing Cooperative Agreement.

"Authority" means the political subdivision organized and operated pursuant to § 15.2-5368 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 § 15.2-5368 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 Agreementagreement" 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, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical,

Comment [1]: Comment: We deleted the reference to "planning and negotiations" related to a Cooperative Agreement. It is doubtful that the state can adequately supervise planning and negotiations that precede an evaluation of an Application for a Cooperative Agreement. Moreover, parties who are conducting such activities would not know whether their Cooperative Agreement ultimately will be approved, so they will have no certainty that they will receive antitrust immunity to cover such activities. Parties who are contemplating a merger are able to receive antitrust advice so that they can adequately negotiate and plan for their merger in a way that does not violate the antitrust laws, and so can parties submitting an application for a Cooperative Agreement. In short, there is no reason that applicants need antitrust immunity for activities conducted prior to approval of a Cooperative Agreement.

diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals.

"Day" or "Days" means business 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.

"Index" means a set of Measures used to objectively track the progress of a Cooperative Agreement over time to assess whether its benefits outweigh the disadvantages attributable to a reduction in competition resulting from the Cooperative Agreement.

"Letter Authorizing Cooperative Agreement" means a document that is issued by the ~~Commissioner~~ as evidence of the ~~Department's~~ intention that the implementation of a ~~Cooperative Agreement~~, when actively supervised by the ~~Department~~, receives state action immunity from prosecution by the state, by the federal government, or by any commonwealth attorney in the state, as a violation of state or federal antitrust laws.

"Letter Holder" means the entity holding the Letter Authorizing Cooperative Agreement issued by the Commissioner.

"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.

"Parties" means two or more hospitals entering into a ~~Cooperative Agreement~~ agreement.

Comment [2]: Comment: As part of the Commissioner's obligation to actively supervise a Cooperative Agreement, if approved, identifying and tracking the measures to evaluate whether the Parties are meeting the conditions of approval is critical. Consistent with the approach in the TN Regs, we are proposing the implementation of an Index for tracking these measures.

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"Plan of Separation" means ~~athe~~ written proposal submitted with an ~~Application~~~~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, 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 inpatients and/or outpatients.

"Secondary Service Area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its inpatients and/or outpatients.

12VAC5-221-30. General.

A Letter Authorizing Cooperative Agreement shall be issued only (i) when the ~~Hospitals~~~~hospitals~~ are in compliance with all applicable state, and local statutes and regulations and the provisions of this chapter and (ii) when a completed ~~Application~~~~application~~ including the ~~Application~~~~application~~ fee has been received by the ~~Department~~~~department~~.

12VAC5-221-40. Separate Applications.

~~A Hospital~~~~Hospitals~~ shall ~~be required to~~ submit an ~~Application~~~~application~~ for a Letter Authorizing Cooperative Agreement for each Cooperative Agreement entered into.

This provision applies even in the event that ~~a Hospital has~~~~the hospitals have~~ an existing Letter Authorizing Cooperative Agreement issued by the Commissioner. An amendment to a Cooperative Agreement shall require submission of a new ~~Application.~~~~application.~~

Comment [3]: *Comment:* The Plan of Separation concept is a critical element of the Parties' application and is consistent with the TN Regs. Absent this concept, it is unclear how plans for unwinding the Cooperative Agreement would be implemented. A Plan of Separation and the ability to execute on such a plan should be an important factor in considering whether the potential disadvantages from a loss of competition outweigh benefits from a Cooperative Agreement.

12VAC5-221-45. Letter of Intent

A. At least forty-five (45) days prior to filing an Application, the Parties to the proposed Cooperative Agreement shall file a letter of intent to the Department containing the following:

1. A brief description of the proposed Cooperative Agreement, including the physical location of the entities and parties to the Cooperative Agreement.
2. A list that includes all assets, ownership interests, subsidiaries and businesses currently owned or operated, in whole or in part, directly or indirectly, by any party to the Cooperative Agreement that the parties propose to be included in, divested, sold or affected as a result of the Cooperative Agreement.
3. A list of all business interests or units for which each party to the Cooperative Agreement has any ownership interest or a management contract that is not proposed to be included in the Cooperative Agreement.
4. The name, address and contact information of the parties to the proposed Cooperative Agreement including the executive officers, each party's respective board members and each party's general counsel.
5. A description of the entities' governing structure under the Cooperative Agreement.
6. The anticipated date of submission of the Application; and the anticipated effective date of the proposed Cooperative Agreement; and
7. The geographic service area and population covered by the Cooperative Agreement.

B. The Parties shall amend the letter of intent if material changes occur prior to submission of the Parties' Application.

C. A letter of intent expires six (6) months after the date of the receipt by the Department if no application is filed with the Authority within that period.

D. The Department shall post letters of intent on the Department's website until an Application is filed or until the letter of intent expires.

12VAC5-221-50. Application.

A. ~~A~~ Parties within any Participating Locality may submit an ~~Application~~ application for a Letter Authorizing Cooperative Agreement to the Authority. Information regarding the requirements of an ~~Application~~ application for a Letter Authorizing Cooperative Agreement should be obtained through the Authority.

B. Parties shall submit a copy of the ~~Application~~ application to the Authority, the Commissioner and the Attorney General.

C. The Commissioner and the Department reserve the right to request additional documentation or information before considering an ~~Application~~ application for a Letter Authorizing Cooperative Agreement.

12VAC5-221-60. Fee Schedule.

A. Fees shall be remitted with the ~~Application~~ application described within 12VAC5-221-40.

B. Fees shall be remitted only by certified check, cashier's check, bank money order or other methods approved by the ~~Department~~ department. Fees shall be made payable to the Department.

C. The application fee shall be \$50,000 and shall be due to the department with the application. If the Commissioner should determine after review of the application that the actual

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Comment [4]: Comment: Under the statute there are strict deadlines governing the review of an Application once it is submitted. To assure that the Authority and the Commissioner have sufficient time for these tasks, and that the public also has time to anticipate a filing, the applicants should be required to file a Letter of Intent at least 45 prior to submitting their applications. The provision included here is modeled after the TN Regs which have such a requirement.

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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.

D. The fee due with the filing of the annual report as required by 12VAC5-221-110 shall be \$20,000. If the Commissioner should determine after review of the annual report the actual cost incurred by the Department is greater than \$20,000, the Letter Holder shall pay any additional amounts due as instructed by the Department. The annual filing fee shall not exceed \$75,000.

E. If it becomes necessary for the Department to file suit to enforce any provision of applicable law, these regulations or any of the terms of an approved application, then applicant, parties or Letter Holder shall be responsible for all costs associated with any such litigation, including, but not limited to all court costs and attorneys fees.

12VAC5-221-70. Public Hearing.

A. The Commissioner in conjunction with the Authority shall schedule a public hearing for each ~~Application~~ ~~application~~ submitted in accordance with 12VAC5-221-40. The hearing shall be held no later than 45 days after the receipt of a complete Application ~~the application~~ by the Authority.

B. Notice of the hearing shall be mailed to the ~~Applicant~~ ~~applicant~~ no later than ~~1530~~ days ~~prior to~~ ~~after~~ the ~~date~~ ~~receipt~~ of the ~~hearing~~ ~~application~~.

C. Notice of the public hearing shall be ~~mailed no later than 15 days prior to the date of the hearing~~ ~~sent~~ to any persons who submitted public comments to the Authority regarding the ~~Application~~ ~~application~~ for a Letter Authorizing Cooperative Agreement.

~~D. Notice of the public hearing shall be published no later than 15 days prior to the date of the hearing in the newspaper of general circulation in the Lenowisco and Cumberland Plateau Planning Districts and on the Authority's website.~~

~~E.~~ 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.

12VAC5-221-80. The Commissioner's Request for Information.

A. Upon receipt of the Authority's recommendation, which is expected within 75 days of receipt of a completed ~~Application unless extended for a specified period of time with fifteen (15) days notice to the Parties according to §15.2-5384.1 of the Virginia Code~~ ~~application~~, the Commissioner and Department may request supplemental information from ~~Applicants~~. ~~The timing for the Commissioner's review of a recommendation from the Authority shall not commence until the Department receives sufficient responses to all requests for supplemental information as determined by the Commissioner~~ ~~the applicant~~.

B. To the extent the information is not present within the ~~Application~~ ~~application~~ the Commissioner shall request the following information:

1. ~~A report used for public information and education that is documented to have been disseminated prior to submission of the Application and submitted as part of the Application~~ ~~application~~ which includes at a minimum:

a. A description of the proposed geographic service area, 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 or accessibility upon initiation of

Comment [5]: Comment: Although the Virginia Statute is explicit about limitations on the cost obligations of the applicants, the statutory fees may be insufficient to cover the costs of the Commissioner's activities related to active supervision. On the other hand, the statute does not address costs and fees associated with enforcement actions under the statute and therefore we support including a provision that would obligate the parties to pay the costs and fees associated with enforcement litigation.

Comment [6]: Comment: The changes included in this section are to assure that interested parties, and the public in general, have adequate notice of the hearing. These changes are also consistent with the statute.

Comment [7]: Comment: As we have described in the cover letter, for several reasons the requests from this section should be required as part of the initial application. The initial application should be deemed incomplete if the information described in this section is not provided.

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Comment [8]: Comment: This requirement that the Parties publish a report is similar to that in the TN Regs, but we have supplemented the Draft VA Regs with the additional requirements included in the TN Regs, particularly as they relate to providing information to the public on changes to access, quality, and cost.

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8/11/2015

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the Cooperative Agreement and/or findings from studies conducted by hospitals and other external entities, including health economists, clinical services and population health experts, that describe how implementation of the proposed Cooperative Agreement plans will be: effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including, but not limited to, eliminating duplicate services and future plans; and equitable with respect to maintaining quality and competition in health services within the service area, assuring patient access to and choice of insurers and providers within the health care system;

d. A description of any plans, including any preliminary plans, draft plans or not yet finalized plans, for any facilities that will impact access for patients to the services currently offered by the Parties at their respective facilities, including closures, reductions in capacity, consolidation, reduction or elimination of any services;

e.—a. Findings from service area assessments that describe major health issues and trends, specific population health disparities and comparisons to state and other similar regional areas proposed to be addressed;

f. A description of the impact—b. Impact on the health professions workforce including long-term employment and wage levels and recruitment and retention of health professionals; and

g—e. A record of community stakeholder and consumer views of the proposed Cooperative Agreement collected through a public participatory process including meetings and correspondence.

2. Detail regarding the nature of the proposed Cooperative ~~Agreement~~ agreement between the ~~Parties~~ parties;

3. A signed copy of the Cooperative Agreement and a copy of the following:

—a. A description of any consideration passing to any 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 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 subject of the Cooperative Agreement, including those not occurring 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 or any other product, facility or service;

—d. A description of each ~~Party's~~ party's contribution of capital, equipment, labor, services or other value to the transaction;

e. A statement regarding the requirement(s) for any Certificate of Public Advantage resulting from the Cooperative Agreement.

4. A detailed description of the proposed geographic service area, not limited to the boundaries of the Commonwealth of Virginia. If the proposed geographic service area differs from the service areas where the ~~Parties~~ parties have conducted business over

Comment [9]: **Comment:** It is important that the Parties are transparent with the public and with the Commissioner about any potential reduction in services that are contemplated by the Cooperative Agreement.

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the five (5) years preceding the ~~Application~~ ~~application~~ a description of how and why the proposed geographic service area differs and why changes are proposed;

5. A description of the prior history of dealings between the parties to the Application, including but not limited to, their relationship as competitors and any prior joint ventures, affiliations or other collaborative agreements between the parties.

6. A description of the Parties' financial performance, including:

~~a. A~~ summary of all aspects of the financial performance of each Party ~~party to the Cooperative Agreement~~ ~~transaction~~ for the preceding five (5) fiscal years including 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;

b. A copy of the current annual budget for each Party to the Cooperative Agreement. The budgets must be in sufficient detail so as to determine the fiscal impact of the Cooperative Agreement on each Party. The budgets must be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used must be documented;

c. A five (5) year projected budget including projected ~~6. Projected~~ costs, revenues, profit margins and operating ratios of each of the Applicants ~~applicant~~ for a period of five years (i) assuming a Letter Authorizing Cooperative Agreement is not issued; and (ii) assuming ~~after~~ a Letter Authorizing Cooperative Agreement is issued;

7. 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;

c. The following policies:

~~i. —~~ a. A policy that assures no restrictions to Medicare and/or Medicaid patients;

~~ii. —~~ b. Policies for free or reduced fee care for the uninsured and indigent;

~~iii. —~~ e. Policies for bad debt write-off; and

~~iv. —~~ d. Policies that assure parties to the Cooperative Agreement will maintain or exceed the existing level of charitable programs and services.

d. Identification of existing and future business plans, reports, studies or other documents of each party that:

i. 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

ii. Identification of plans that will be altered, eliminated or combined under the Cooperative Agreement.

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Comment [10]: Comment: Although the TN Regs ask for only a 3-year projected budget, the VA Draft Regs contained a request for a 5-year budget projection. We think that the 5-year projection is reasonable and should be maintained in the VA Regs.

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8. A description of the plan to systematically integrate health care and preventative 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 interest of the community; and
- c. Clinical standardization;

d. Alignment of cultural identities of the parties to the Cooperative Agreement; and
e. Implementation of innovative or “value-based” payment, including but not limited to risk-based payment models to include risk, a schedule of risk assumptions and proposed performance metrics to demonstrate movement toward risk assumption and a proposed global spending cap for hospital services.

9. A description of the plan, including economic metrics, that details anticipated efficiencies in operating costs and shared services to be gained 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.

10. A description of the market and the competitive dynamics for health care services in the parties' respective service areas, including at a minimum:

~~a.~~ a. The zip codes that constitute the primary service area (PSA) and secondary service areas (SSA) for each of the parties' hospitals, and for each such PSA and SSA;

~~i.~~ b. The identity of any other hospital located in the service area and any hospital that also serves the parties' PSA and SSAs;

~~ii.~~ c. Estimates of the share of hospital services furnished by each of the parties and any other hospitals;

~~b.~~ d. Identification of whether any services or products of the proposed Cooperative Agreement are currently being offered or capable of being offered by any other hospitals in the geographic service area and a description how the proposed Cooperative Agreement will not exclude such other hospitals from continued competitive and independent operation in the geographic service area;

~~c.~~ e. A listing of the physicians employed by or under contract with each of the parties' hospitals, including their specialty and office location(s);

~~d.~~ f. The identity of any potential entrants in the parties' service areas and the basis for any belief that such entry is likely in the near term; and

~~e.~~ g. A list of each applicant's top 10 commercial insurance payors by revenue.

11. A detailed description of each of the benefits that the applicant proposes will be achieved through the Cooperative Agreement.

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Comment [11]: Comment: We have supplemented the criteria in this section to align with the TN Regs and include important requirements such as description of effects on risk-based payment models.

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12. For each benefit described provide:

- a. A description specifically describing how the applicant intends 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;
- c. An explanation of why the benefit can only be achieved through a Cooperative Agreement and not through other less anticompetitive arrangements; and
- d. A description of how the ~~Applicant~~ applicant proposes that the Commissioner measure and monitor achievement of the proposed benefit including:

- i. 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;
- ~~i. The projected levels and trajectory for each measure that would be achieved over the next five (5) years. The current level of the metric to be measured to determine the benefit;~~
- ii. ~~The estimated level~~ in the absence of the Cooperative Agreement;
- iii. The projected levels and trajectory for each measure that would ~~estimated level the applicant believes will~~ be achieved over the next five (5) years under the Cooperative Agreement ~~cooperative agreement~~;
- iv. The basis for the metrics proposed to measure the benefit; and
- v. A plan for how the requisite data for assessing the benefit will be obtained.

13. A description of any potential adverse impact of the proposed Cooperative Agreement on population health, quality, availability, ~~cost or~~ and price of health care services to patients or payers.;

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14. An explanation of how the Cooperative Agreement will assure continued competitive and independent operation of the services or products of entities not a party to the Cooperative Agreement.

15. A description of any commitments the ~~Parties~~ parties are willing to make to address any potential adverse impacts resulting from the Cooperative Agreement and for each such commitment, ~~include~~ including at a minimum:

- a. The ~~Parties'~~ parties' proposed benchmarks and metrics to measure achievement of the proposed commitments;
- b. How the ~~Parties~~ parties propose data be obtained and analyzed to evaluate the extent to which the commitments have been met, including with respect to how data should be obtained from entities other than the Applicants; and
- c. The consequences the ~~Parties~~ parties propose will follow should their proposed commitments not be met.

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16. A Plan of Separation. ~~The Parties~~ Plan of Separation shall be updated annually by the parties to the Cooperative Agreement. 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~~ The Plan of Separation shall be updated annually by the parties to the Cooperative Agreement. ~~parties~~;

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17. A statement regarding the requirements for any Certificate(s) of Public Need resulting from the Cooperative Agreement;

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18. A detailed description of the total cost resulting from the Cooperative Agreement, including, but not limited to, costs for the Parties, the Authority, and for the Department with respect to its obligation to review the Authority's recommendation for an Application and to actively supervise any Letter Authorizing 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 are borne by each party.

Comment [12]: Comment: The Parties should be required to indicate the projected or estimated costs to be expended by both the Parties and any other relevant entity involved in the Cooperative Agreement process. In particular, it will be helpful to understand the level of spending that the Parties' project the Commissioner to spend for purposes of active supervision.

19. 18. An explanation of the reasons for the exclusion of any information set forth in this section, including an explanation of why the item is not applicable to the proposed Cooperative Agreement or to the parties;

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20. 19. 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.

21. 20. Data and documentation to support any requested supplemental information.

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22. A verified statement signed by the Chairperson of the Board of Directors and Chief Executive Officer of each party of the Application; or if one or more of the Applicants is an individual, signed by the individual Applicant; attesting to the accuracy and completeness of the enclosed information.

12VAC5-221-90. The Commissioner's Review

A. The Commissioner shall consult with the Attorney General when reviewing an Application application for a Letter Authorizing Cooperative Agreement.

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B. The Commissioner shall consult and coordinate with other affected jurisdictions when reviewing an Application application for a Letter Authorizing Cooperative Agreement. Should the Commissioner shall determine should the Commissioner decide to issue a Letter Authorizing Cooperative Agreement, the Commissioner shall ensure that the provisions of the Letter Authorizing Cooperative Agreement is be approved it shall be consistent with the statutes, rules and regulations of other affected jurisdictions.

C. The Commissioner shall consult with all other affected agencies of the Commonwealth when reviewing an application for a Letter Authorizing Cooperative Agreement.

D. The Commissioner in his review shall examine the record developed by the Authority, the Authority's recommendation, any additional information received from the Applicant applicant as well as any other data, information, or advice available to the Commissioner.

E. Failure to provide information as requested by the Authority or the Commissioner shall be a basis for a finding that the Applicant has failed to establish that likely benefits of the Cooperative Agreement outweigh the disadvantages, and not granting a Letter Authorizing Cooperative Agreement.

Comment [13]: Comment: This provision is important because otherwise the Applicants could refuse to provide requested information and the Commissioner might need to reach a decision within 45 days based on an incomplete record.

F. The Commissioner shall consider the following factors when conducting a review of an Application application:

1. Advantages:

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8/11/2015

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- 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 payors 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~~cooperative agreement.

E. The Commissioner shall approve the ~~Application~~application for a Letter Authorizing Cooperative Agreement if he finds that the benefits likely to result from the Cooperative Agreement outweigh the disadvantages likely to result from a reduction in competition from the Cooperative Agreement.

F. In the selection and application of the metrics 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, 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~~metrics and goals from the Technical Advisory Panel pursuant to 12VAC5-221-130; and
4. To the extent quantifiable goals or targets are specified, allow for flexibility should environmental factors that are outside the control of the ~~Applicant~~applicant change significantly.

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12VAC5-221-100. Action on an ~~Application~~ application.

A. The Commissioner shall issue his decision in writing within 45 days of receipt of the Authority's recommendation. ~~However, at the request of the Applicant, the Commissioner can delay issue his decision to provide additional time to review the record.~~

B. In the event the Commissioner has requested supplemental information from the applicant in accordance with 12VAC5-221-80, the Commissioner shall issue his decision in writing 60 days following the receipt of the supplemental information from the applicant.

C. The Commissioner ~~shall~~ may condition approval of the Letter Authorizing Cooperative Agreement upon the ~~Applicants'~~ applicant's commitment to achieving the improvements in population health, access to health care services, quality, and cost efficiencies identified by the ~~Applicant~~ applicant in support of their ~~Application~~ application. Such conditions ~~should~~ may include, ~~but are not be limited to:~~

Comment [14]: *Comment:* This provision, allowing for an extension of the 45-day review requirement, coupled with the earlier suggested provision that the failure to provide information requested by the Authority or Commissioner can be the basis for a denial, will give the Commissioner the assurance that she can receive all the information she has requested and conduct an adequate review in the event the provision in the next section is not retained.

Comment [15]: *Comment:* We support this provision, but there is a concern that it might be viewed as inconsistent with the statutory requirement that the Commissioner issue a decision within 45 days of receiving the Authority's recommendation.

1. ~~4.~~ A cap on the negotiated case-mix adjusted revenue per discharge.

a. ~~Such caps shall be set separately for each health plan with 5% or more of the commercial revenues of the Applicants in the geographic area covered by the Cooperative Agreement, and each type of product offered by the health plan. A separate cap should be established covering all of the remaining health plans in the area based on the weighted average data from all such plans.~~

b. ~~The initial rate caps should be based on the current rates offered by the Applicant, adjusted to reflect proposed savings that the Parties have identified in their Application for Cooperative Agreement.~~

c. ~~In subsequent years, the caps can be modified on a health plan and product-specific basis, to reflect the relative increases (or decreases) in rates that the health plans are experiencing on similar products elsewhere in the Commonwealth of Virginia.~~

d. ~~The caps shall include the rates of the hospital-based physicians, such as radiologists, anesthesiologists, pathologists and emergency room physicians that are employed by or have exclusive contracts with the Parties.~~

e. ~~Similar caps shall be applied to outpatient, physician and other services to the extent competition for such services will be adversely affected under the Cooperative Agreement.~~

f. ~~The Department may rely on third-party auditors to assist in determining the level of the caps and monitoring compliance.~~

g. ~~The method for calculating such caps~~ ~~case-mix~~ shall be published on the Virginia Department of Health's Office of Licensure and Certification's website in a guidance document.

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2. ~~A commitment to return a portion of cost savings and efficiencies gained through the Cooperative Agreement to the citizens in the affected service area through, for example, rebates or discounts on future rates.~~

3. ~~A commitment that the Letter Holder shall not refuse to include certain provisions in contracts with health plans that health plans have utilized 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.~~

342. An agreement that the Letter Holder shall not prevent or discourage health plans from directing or incentivizing patients to choose certain providers; ~~the Letter Holder~~

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shall not have any contractual clauses or provisions ~~that~~which prevent health plans from directing or incentivizing patients.

45. An agreement that the Letter Holder shall not engage in the tying of sales. That is, the Letter Holder shall not require that sale of the health system's services shall be coupled with the health plan's purchase of other services from the health system.

56. An agreement that the Letter Holder 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.

67. An agreement that the Letter Holder will contract with any health plan that desires to contract with it as long as the terms of the contract are reasonable and are consistent with the Cooperative Agreement, as determined by the Department.

78. An agreement by the parties that, in the event the Cooperative Agreement is revoked or terminated, the statute of limitations should be tolled with respect to a challenge to any merger or other form of collaboration that was covered under the Cooperative Agreement for a time period equal to the duration of the Cooperative Agreement.

Comment [16]: Comment: In the absence of a waiver of the statute of limitations, it is uncertain whether private parties would be able to challenge a merger that had been immunized under a Cooperative Agreement which had been subsequently revoked or terminated.

D. The Commissioner's decision to approve or deny an Application~~application~~ shall constitute a case decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et. seq.).

E. ~~12VAC5-221-110~~ Ongoing and Active Supervision.

A. Any Applicant~~applicant~~ who receives a Letter Authorizing Cooperative Agreement shall submit, within thirty (30) days following receipt of the Letter, the following information to serve as benchmarks for assessment in future monitoring:

Comment [17]: Comment: This Section A. was moved from the prior section because we believe it is more related to the Ongoing Monitoring and Active Supervision of a Cooperative Agreement. We have also added a 30-day requirement for the submission of the information listed here.

1. Current mortality and morbidity rates for the geographic region encompassed by the Authority;
2. An assessment of patient satisfaction;
3. A list of all major medical technologies in use;
4. An assessment of employee satisfaction;
5. A charge master;
6. Information reflecting the contracted rates negotiated with non-physician providers, allied health professionals and others; and
7. Any other metrics requested by the Department.

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12VAC5-221-110. B. The Department shall create an Index that will be used to evaluate the proposed and continuing benefits of the Cooperative Agreement;

Comment [18]: Comment: The use of an Index is modeled after the TN Regs. It will provide a "report card" that will allow for transparency and public accountability. We anticipate that developing and modifying the Index over time, as well as gathering data and monitoring performance according to the Index, will require substantial resources of the Department, with input from the Technical Advisory Panel.

C. The Index will include Measures of the cognizable benefits from the Cooperative Agreement in at least the following categories:

1. Population health;
2. Access to health services;
3. Economic; and
4. Other cognizable benefits.

D. Each category may be comprised of Measures for subcategories which shall be recommended separately by the Technical Advisory Panel and the Parties to the Cooperative

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Agreement. The Department shall have the exclusive authority to add to, modify, or to accept or reject recommendations when creating the Index.

E. The Department shall establish a baseline score at the outset of the Index composition to allow for the future demonstration of a benefit. Subsequently, established ranges for the score should demonstrate whether:

1. The advantage is established by a preponderance of the evidence, in which event the Cooperative Agreement will continue in effect;

2. The advantage is not established by a preponderance of the evidence, in which event the Cooperative Agreement will be terminated in accordance with Section 12VAC5-221-140

Department representatives Monitoring.

F. A. A Department representative may make periodic unannounced on-site inspections of the Letter Holder's facilities as necessary. If the Department finds, after inspection, noncompliance with any provision of this chapter, any applicable state regulations, the elements of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement, the Commissioner shall begin enforcement procedures in accordance with 12VAC5-221-140.

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GB. The Letter Holder 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 Letter Holder's control, direction, or supervision.

HC. 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 Letter Holder, and the complainant, if known, will be notified of the findings of the investigation in writing.

12VAC5-221-120. Periodic Annual Reporting.

A. Letter Holders shall submit periodic reports~~report annually~~ to the Commissioner on January 1 and July 1 (or the following business day) of each year that the Cooperative Agreement is in effect on the extent of the benefits realized and compliance with any terms and conditions placed on their Letter Authorizing Cooperative Agreement. -The report shall:

Comment [19]: Comment: The TN Regs call for twice per year reporting to the Commissioner. We have aligned this requirement here.

1. Describe the activities conducted pursuant to the Cooperative Agreement;
2. Include any actions taken in furtherance of commitments made by the Letter Holder or terms imposed by the Commissioner as a condition for approval of the Letter Authorizing Cooperative Agreement;
3. Include information related to changes in price, cost, quality, access to care and population health;
4. Include actual costs, revenues, profit margins and operating costs;
5. Include a charge master;
6. Information reflecting the contracted rates negotiated with non-physician providers, allied health professionals and others; and
7. Include any metrics requested by the Department based on the recommendations of the Technical Advisory Panel appointed pursuant to 12VAC5-221-130.

B. The Letter Holder 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~~The Commissioner may require the Letter Holder 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.~~

~~C. The Commissioner may require the Letter Holder to supplement the periodic reports with additional information to the extent necessary to ensure compliance with the Cooperative Agreement and the Letter Authorizing Cooperative Agreement.~~

~~G. D. All ~~periodic~~annual reports submitted pursuant to this subsection shall be certified audited by a third-party auditor.~~

~~E. 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 has resulted from the Cooperative Agreement.~~

12VAC5-221-130. 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 for inclusion in an Index 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 in selecting quality measures and benchmarks for annual reporting.~~

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 of the Letter Holder;
3. A Chief Medical or Quality Officer from other state market areas with no affiliation to the Letter Holder;
4. A Chief Medical or Quality Officer from a health plan that has subscribers in the affected area;
5. Experts in the area of health quality measurement and performance; and
6. A consumer and employer representative from the affected area to be determined by the Commissioner of Health.

C. The Technical Advisory Panel shall meet at least on an annual basis.

D. The Technical Advisory Panel shall identify evidence-based quality metrics in the areas of patient safety, health outcomes, patient satisfaction, access to care and any other areas identified by the panel. The panel shall also make recommendations 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.

12VAC5-221-140. Enforcement Procedures.

A. If the Commissioner has reason to believe that the Letter Holder is no longer in compliance with the Letter Authorizing Cooperative Agreement, the Commissioner shall initiate a proceeding to determine compliance.

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 at the consent of the Letter Holder.

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Comment [20]: Comment: This will ensure transparency in the active supervision and monitoring process.

Comment [21]: Comment: Although the TN Regs do not have an ongoing role for the Advisory Group (the equivalent of the Technical Advisory Panel in VA), we believe that this ongoing role is important to supporting the Commissioner in her role of actively supervising a Cooperative Agreement and addressing continually changing metrics and measures of quality, access, and cost that may be relevant to the Parties.

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C. The Commissioner may revoke a Letter Authorizing Cooperative Agreement upon a finding that:

1. The Letter Holder is not complying with the terms of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement;
2. The Cooperative Agreement is not in substantial compliance with the terms of the Letter Holder's application or the Letter Authorizing Cooperative Agreement;
3. The benefits resulting from the Letter Authorizing 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 the Letter Authorizing Cooperative Agreement; or
5. The Letter Holder has failed to pay any fee required by the Department or the Authority.

D. The proceeding initiated by the Commissioner under this section shall be held in accordance with and governed by the Virginia Administrative Process Act (§ 2.2-4000).

E. The proceeding initiated by the Commissioner under this section shall be held in accordance with and governed by the Virginia Administrative Act (§ 2.2-4000). Any Letter Holder aggrieved by a decision of the Department or Commissioner under this section is entitled to judicial review of the decision by the Virginia Administrative Process Act (§ 2.2-4000).

12VAC5-221-150. Voluntary Termination of Cooperative Agreement.

A. Any Letter Holder shall file notice with the Department 30 days prior to terminating 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 Letter Holder shall return the Letter Authorizing Cooperative Agreement to the Office of Licensure and Certification.

C. Should ~~Parties~~~~parties~~ terminate a Cooperative Agreement they shall no longer be immunized from challenge or scrutiny under the Commonwealth's or federal antitrust laws, and in accordance with Section 12VAC5-221-100(c)(7), the Parties shall not be permitted to assert statute of limitations defenses to challenges under antitrust laws, antitrust laws.

12VAC5-221-160. 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 12VAC5-221-120 shall be published on the Virginia Department of Health's Office of Licensure and Certification website.

E. The Commissioner shall make public his determinations of compliance under the Letter Authorizing the Cooperative Agreement.

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12VAC5-221-170. Immunity.

Activities conducted pursuant to a Letter Authorizing Cooperative Agreement are immunized from challenge or scrutiny under the Commonwealth's antitrust laws, pursuant to § 15.2-5385 of the Code of Virginia.

Upon any revocation or termination by the Department of a Letter Authorizing a Cooperative Agreement under these rules, the parties remain immunized from challenge or scrutiny under the Commonwealth's and federal antitrust laws until such time as the parties have completed a plan of separation.

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