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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-38-01	Hospital Cooperation Act of 1993
Rule Number	Rule Title
1200-38-01-.01	Purpose and Definitions
1200-38-01-.02	Application Process
1200-38-01-.03	Terms of Certification
1200-38-01-.04	Notice and Hearing
1200-38-01-.05	Issuance of COPA
1200-38-01-.06	Active Supervision by Terms of Certification
1200-38-01-.07	Modification/Termination
1200-38-01-.08	Hearing and Appeals

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

Chapter 1200-38-01
Hospital Cooperation Act of 1993

New Chapter

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1200-38-01-.01 Purpose and Definitions.

The rules in this chapter implement the law relative to Cooperative Agreements and the granting of Certificates of Public Advantage pursuant to the Hospital Cooperation Act of 1993, T.C.A. §§ 68-11-1301 through 68-11-1309.

Pursuant to the Act, the Department is responsible for active state supervision to protect the public interest and to assure that the reduction in competition of health care and related services continues to be outweighed by clear and convincing evidence of the likely benefits of the Cooperative Agreement, including but not limited to improvements to population health, access to services and economic advantages to the public. The COPA will be denied or terminated if the likely benefits of the Cooperative Agreement fail to outweigh any disadvantages attributable to a potential reduction in competition resulting from the Cooperative Agreement by clear and convincing evidence.

- (1) "Advisory Group" means the group of stakeholders from Applicants geographic service area, as specified in the Application, appointed by the Commissioner, in consultation with appropriate constituencies and government agencies, to recommend Measures to be considered for inclusion in an Index to objectively track Public Advantage of a single Cooperative Agreement.
- (2) "Applicant" means the parties to a Cooperative Agreement who submit an Application to the Department in accordance with 1200-38-01.02.
- (3) "Application" means the written materials submitted to the Department in accordance with 1200-38-01.02, by entities who desire to apply for a Certificate of Public Advantage.
- (4) "Attorney General" means the Attorney General and Reporter for the State of Tennessee.
- (5) "Certificate of Public Advantage ("COPA" or the "Certificate")" means the written approval by the Department which governs the Cooperative Agreement.
- (6) "Certificate Holder" means the entity holding the Certificate of Public Advantage issued by the Department.
- (7) "Commissioner" means the Commissioner of the Department of Health.
- (8) "Cooperative Agreement" means an agreement among two (2) or more hospitals for the consolidation by merger or other combination of assets, offering, provision, operation, planning, funding, pricing,

contracting, utilization review or management of health services or for the 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 transaction occurs or at any time thereafter.

- (9) "Department" means the Department of Health.
- (10) "Hospital" means an institution required to be licensed as a hospital pursuant to § 68-11-201, or defined as a psychiatric hospital in § 68-11-102; or any parent of a hospital, hospital subsidiary or hospital affiliate that provides medical or medically-related diagnostic and laboratory services or engages in ancillary activities supporting those services.
- (11) "Index" means a set of Measures used to objectively track the progress of a Cooperative Agreement over time to ensure Public Advantage. The components of the Index may be assigned differential weightings and modified from time to time as determined by the Department.
- (12) "Intervenor" means any hospital, physician, allied health professional, healthcare provider or other person furnishing goods or services to, or in competition with, hospitals, insurer, hospital service corporation, medical service corporation, hospital and medical services corporation, preferred provider organization, health maintenance organization or any employer or association that directly or indirectly provides health care benefits to its employees or members.
- (13) "Measure" means some number of factors or benchmarks, which may be binary, a range or continuous factors.
- (14) "Plan of Separation" means the written proposal submitted with an Application to return the parties to a Cooperative Agreement 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.
- (15) "Population" means the entirety of the human population residing or domiciled in the geographic service area set out in the proposed Cooperative Agreement unless otherwise defined.
- (16) "Public Advantage" means the likely benefits accruing from a Cooperative Agreement which outweigh, by clear and convincing evidence, the likely disadvantages attributable to a reduction in competition likely to result from the Cooperative Agreement.

Authority: T.C.A. §§ 68-11-1301 through 68-11-1309.

1200-38-01-.02 Application Process.

- (1) Letter of Intent. At least forty-five (45) days prior to filing an Application, the parties to the proposed Cooperative Agreement shall file a letter of intent.
 - (a) Contents. A letter of intent shall contain the following:
 - 1. A brief description of the proposed Cooperative Agreement, including the location of the entities and parties to the Cooperative Agreement;
 - 2. A list that includes all assets, ownership interests, subsidiaries and affiliated businesses currently owned or operated, in whole or in part, by any party to the Cooperative Agreement that the parties propose to be included in the COPA or any assets, ownership interests, subsidiaries and affiliated businesses currently owned or operated, in whole or part, by any party to the Cooperative Agreement that will be 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) Amendment. The parties shall amend the letter of intent if material changes occur prior to submission of the parties' Application.
- (c) Expiration. A letter of intent expires six (6) months after the date of receipt by the Department, if no Application was timely filed with the Department.
- (d) Public Record. The Department shall post letters of intent on the Department's website until an Application is filed or until the letter of intent expires.
- (2) Application.
- (a) Parties seeking a COPA shall apply to the Department in writing. Parties shall submit the following information in the Application:
1. A descriptive title;
 2. A table of contents;
 3. An executive summary which includes:
 - (i) Goals for change to be achieved by the Cooperative Agreement;
 - (ii) Benefits and advantages to parties and the public including but not limited to:
 - (I) Population health;
 - (II) Access to health care and prevention services; and
 - (III) Healthcare operating costs, including avoidance of capital expenditures, reduction in operating expenditures and improvements in patient outcomes.
 - (iii) Description of how the Cooperative Agreement better prepares and positions the parties to address anticipated future changes in health care financing, organization and accountability initiatives; and
 - (iv) Potential disadvantages of the Cooperative Agreement.
 4. The names of each party to the Application and the address of the principal business office of each party;
 5. A verified statement signed by the Chairperson of the Board of Directors and Chief Executive Officer of each party to 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;

6. 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 or other collaborative arrangements between the parties;
7. A detailed description of the proposed geographic service area, not limited to the boundaries of the State of Tennessee. If the proposed geographic service area differs 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 geographic service area differs and why changes are proposed;
8. Identification of whether any services or products of the proposed Cooperative Agreement are currently being offered or capable of being offered by other providers or purchasers in the geographic service area described in the Application;
9. 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;
10. A statement of whether there will be a Public Advantage or adverse impact on population health, quality, access, availability or cost of health care to patients and payers as a result of the Cooperative Agreement;
11. A statement of whether the projected levels of cost, access to health care or quality of health care could be achieved in the existing market without the granting of a COPA; and, for each of the above, an explanation of why or why not;
12. 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. The report must include the following:
 - (i) A description of the proposed geographic service area, services and facilities to be included in the Cooperative Agreement;
 - (ii) A description of how health services will change if the Application is accepted;
 - (iii) 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 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 proposed Cooperative Agreement plans are: 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;
 - (iv) 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;
 - (v) Impact on the health professions workforce including long-term employment and wage levels and recruitment and retention of health professionals; and
 - (vi) A record of community stakeholder and consumer views of the proposed Cooperative Agreement collected through a public participatory process including

meetings and correspondence in which this report or its components were used.

13. A signed copy of the Cooperative Agreement, including:
 - (i) A description of any consideration passing to any person under the Cooperative Agreement including the amount, nature, source and recipient;
 - (ii) A detailed description of any merger, lease, change of control or other acquisition or change in ownership of the assets of any party to the Cooperative Agreement;
 - (iii) A list of all services and products and all service locations that are the subject of the Cooperative Agreement, including those not occurring within the boundaries of the State of Tennessee, 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;
 - (iv) A description of each party's contribution of capital, equipment, labor, services or other value to the transaction;
 - (v) A description of the competitive environment in the parties' geographic service area, including:
 - (I) Identification of all services and products likely to be affected by the Cooperative Agreement and the locations of the affected services and products;
 - (II) The parties' estimate of their current market shares for services and products and the projected market shares if the COPA is granted;
 - (III) A statement of how competition among health care providers or health care facilities will be reduced for the services and products included in the Cooperative Agreement; and
 - (IV) A statement regarding the requirement(s) for any Certificate(s) of Need resulting from the Cooperative Agreement.
 - (vi) Impact on the service area's health care industry workforce, including long-term employment and wage levels and recruitment and retention of health professionals;
 - (vii) Description of financial performance, including:
 - (I) A description and summary of all aspects of the financial performance of each party to the transaction for the preceding five (5) years including debt, bond rating and debt service and copies of external certified public accountants annual reports;
 - (II) A copy of the current annual budget for each party to the Cooperative Agreement and a three (3) year projected budget for all parties after the initiation of 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;

- (III) A detailed explanation of the projected effects including expected change in volume, price and revenue as a result of the Cooperative Agreement, including;
 - I. Identification of all insurance contracts and payer agreements in place at the time of the Application and description of pending or anticipated changes that would require or enable the parties to amend their current insurance and payer agreements;
 - II. A description of how pricing for provider insurance contracts are calculated and the financial advantages accruing to insurers, insured consumers and the parties of the Cooperative Agreement if the COPA is granted including changes in percentage of risk-bearing contracts;
 - III. The following policies:
 - A. Policy that assures no restrictions to Medicare and/or Medicaid patients,
 - B. Policies for free or reduced fee care for uninsured and indigent,
 - C. Policies for bad debt write-off; and
 - D. Policies that assure parties to the Cooperative Agreement will maintain or exceed existing level of charitable programs and services.
- (IV) Identification of existing or 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 or subsequent COPA
- (viii) A description of the plan to systematically integrate health care and preventive services among the parties of the Cooperative Agreement, in the proposed geographic service area, to address the following:
 - (I) A streamlined management structure to include a description of a single board of directors, centralized leadership and operating structure;
 - (II) Alignment of the care delivery decisions of the system with the interest of the community;
 - (III) Clinical standardization;
 - (IV) Alignment of cultural identities of the parties to the Cooperative Agreement; and
 - (V) Implementation of risk-based payment models to include risk, a schedule of risk assumption and proposed performance metrics to demonstrate movement toward risk assumption and a proposed global spending cap for hospital services.

- (ix) A description of the plan, including economic metrics, that details anticipated efficiencies in operational costs and shared services to be gained through the Cooperative Agreement including:
 - (I) Proposed use of any cost savings to reduce prices borne by insurers and consumers;
 - (II) Proposed use of cost savings to fund low or no-cost services such as immunizations, mammograms, chronic disease management and drug and alcohol abuse services to achieve long-term population health improvements; and
 - (III) Other proposed uses of savings to benefit advancement of health and quality of care and outcomes.
 - (x) Proposed Measures and suggested baseline values with rationale for each Measure to be considered by the Department in development of an Index. Proposed Measures are to be used to continuously evaluate the Public Advantage of the results of actions approved in the COPA through the Cooperative Agreements under active supervision of the Department. Measures should include source and projected trajectory over each of the first five (5) years of the Cooperative Agreement and the trajectory if the COPA was not granted; Proposed Measures may include:
 - (I) Improvements in the service area population's health that exceed Measures of national and state improvement;
 - (II) Continuity in availability of services throughout the service area;
 - (III) Access and use of preventive and treatment health care services throughout the service area;
 - (IV) Operational savings projected to lower health care costs to payers and consumers; and
 - (V) Improvements in quality of services as defined by surveys of the Joint Commission.
14. An explanation of the reasons for the exclusion of any information set forth in section 1200-38-01-.02, the Application Process, including an explanation of why the item is not applicable to the Cooperative Agreement or to the parties;
 15. A detailed description of the total cost resulting from the Cooperative Agreement, including, but not limited to, new costs for consultants, capital costs and management costs. The description should identify costs associated with the implementation of the Cooperative Agreement, including documentation of the availability of the necessary funds. The description should identify which costs are borne by each party;
 16. A timetable for implementing all components of the Cooperative Agreement;
 17. The Department shall require a Plan of Separation be submitted with the Application. The 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; and
 18. The name, address and telephone number of the person(s) authorized to receive notices, reports and communications with respect to the Application.

(3) Additional Department Requirements.

- (a) The Department may request additional information from the parties prior to deeming the Application complete or issuing a final decision. The Application shall not be deemed complete nor shall the one hundred twenty (120) day review period commence until all information is received by the Department.
- (b) The Department shall notify the parties in writing when the Application is deemed complete.
- (c) The parties shall submit simultaneously a copy of the Application and copies of all additional related materials to the Attorney General and to the Department. The Department is entrusted with the active and continuing oversight of all Cooperative Agreements.
- (d) The Department may waive any of the requirements or timeframes that it finds, at its sole discretion, due to the nature of a particular Cooperative Agreement, are inapplicable to its analysis of the Cooperative Agreement.
- (e) The Application and accompanying documents are public records pursuant to T.C.A. § 10-7-503 and are subject to public inspection in accordance with § 10-7-503, except for records which are confidential pursuant to state or federal law. The parties shall specify any portion of the Application which the parties contend is exempt from the Public Records Act. The parties shall include the specific authority for said exemption. Applicants shall submit two (2) copies of the Application. The first copy shall include all requested information. The second copy shall contain all requested information; however, the parties shall redact confidential information wherever possible. Nothing in this subsection shall limit or deny access to otherwise public information because an Application or accompanying document contains confidential information.

Authority: T.C.A. § 68-11-1303.

1200-38-01-.03 Terms of Certification. All COPAs shall be governed by terms of certification. The terms of certification shall include:

(1) Charges.

- (a) Parties to a Cooperative Agreement who have applied to the Department for a COPA shall pay all charges incurred in the examination of the Application and, in the event the COPA is approved, all charges incurred for the review and ongoing supervision of the Cooperative Agreement, including all expenses of the Department, including, but not limited to, experts and examiners employed in the review and ongoing supervision of the Application and COPA.
- (b) The compensation of the Department, experts and examiners designated by the Commissioner for examining the Cooperative Agreement and all records shall be fixed by the Commissioner at an amount commensurate with usual compensation for like services.
- (c) The Department shall develop a formula to include charges incurred in the examination of the Application and charges incurred for review and ongoing supervision and invoice COPA Applicants and holders Department's costs at a regular interval.

(2) Evaluation by the Department that demonstrates Public Advantage in accordance with the standards set forth in these rules.

(a) Benefits to include:

- 1. Enhancement of the quality of Hospital and hospital-related care provided to Tennessee citizens;
- 2. Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities;

3. Gains in the cost containment and cost-efficiency of services provided by the Hospitals involved;
4. Improvements in the utilization of Hospital resources and equipment;
5. Avoidance of duplication of Hospital resources;
6. Demonstration of population health improvement of the region served according to criteria set forth in the Cooperative Agreement and approved by the Department;
7. The extent to which medically underserved populations have access to and are projected to utilize the proposed services; and
8. Any other benefits that may be identified.

(b) Disadvantages to include:

1. The extent of any likely adverse impact on the ability of health maintenance organizations, preferred provider organizations, managed health care organizations or other healthcare payers to negotiate appropriate payment and service arrangements with Hospitals, physicians, allied healthcare professionals or other healthcare providers;
2. The extent of any reduction in competition among physicians, allied health professionals, other healthcare providers or other persons furnishing goods or services to, or in competition with, hospitals that is likely to result directly or indirectly from the Cooperative Agreement;
3. The extent of any likely adverse impact on (i) patients in the quality and availability of healthcare services and (ii) patients and payers in the price of healthcare services; and
4. 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 Cooperative Agreement.

(3) Ongoing Supervision through the use of an Index tracking demonstration of Public Advantage.

- (a) An Index will be created and used for the Department to evaluate the proposed and continuing Public Advantage of the COPA,
- (b) The Index will include measures of the cognizable benefits in the following categories:
 1. Population Health;
 2. Access to Health Services;
 3. Economic; and
 4. Other Cognizable Benefits.
- (c) Each category may be comprised of Measures for subcategories of the Index which shall be recommended separately by the Advisory Group and the parties to the Cooperative Agreement for the COPA. The Department retains exclusive authority to add to, modify, or to accept or reject recommendations when creating the Index.
- (d) The Department shall establish a baseline score at the outset of the Index composition to allow for the future demonstration of a Public Advantage. Subsequently, established ranges for the score should demonstrate whether:

1. Advantage is clear and convincing; the COPA continues in effect,
2. Advantage is not clear and convincing; a modification to the Cooperative Agreement under the terms of certification will be necessary,
3. Advantage is not evident; COPA is terminated.

(e) Advisory Group

1. Recommendations. The Advisory Group shall recommend to the Commissioner Measures to be considered for inclusion in an Index to objectively track the Public Advantage of a Cooperative Agreement.

2. Meetings. The Advisory Group shall hold at least four (4) meetings with stakeholders to obtain community input and comment, with guidance from the Department.

- (i) All meetings shall be open in accordance with T.C.A. §§ 8-44-101 through 8-44-111.
- (ii) One (1) meeting shall provide for comment from internal stakeholders, such as persons employed by or agents of the parties to the Cooperative Agreement, its affiliates, contractors or vendors, staff clinicians or other persons deriving income from their activities with any of the parties to the Cooperative Agreement.
- (iii) One (1) meeting shall provide for comment from external stakeholders, such as competing health care providers, non-staff clinicians, payers including self-insured employers, governmental agencies, non-governmental agencies, and other parties who derive income from health or health care services or are who are not employed or affiliated with and do not derive income from the parties to the Cooperative Agreement.
- (iv) One (1) meeting shall provide for comment from other members of the community not represented in the internal or external stakeholder groups, including, current or potential patients, customers or other entities who are not affiliated, competing with or otherwise contracting with the parties to the Cooperative Agreement.
- (v) The final meeting shall be open to all persons expressing an interest in the Cooperative Agreement and shall be held following the completion of the Advisory Group's recommendation of Measures to be considered for inclusion in the Index.
- (vi) The Advisory Group, in consultation and with the approval of the Department, may elect to alter the number and composition of the meetings previously described.
- (vii) The Department may provide guidance to the Advisory Group.

3. Completion of Duties.

- (i) The Advisory Group's service shall conclude when the Department receives the Advisory Group's recommendation of Measures proposed for inclusion in the Index.
- (ii) The Commissioner shall have the authority to reconvene the Advisory Group if necessary.

(4) Additional conditions of reporting and operations determined by the Department to demonstrate Public Advantage.

Authority: T.C.A. §§ 68-11-1303 and 68-11-1307.

1200-38-01-.04 Notice and Hearing.

- (1) Prior to acting on an Application for a Certificate, the Department shall hold at least one (1) public hearing which will afford the right to any interested parties to express their views regarding an Application, and may gather additional feedback through other means from the community as needed.
- (2) The Department shall give notice of the completed Application to interested parties by publishing a notice in the Tennessee administrative register in accordance with the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, title 4, chapter 5. The notice shall include a brief summary of the requested action, how to access the Application and information concerning the time and place of the public hearing. The notice shall be published at least fifty (50) days prior to the date set for the public hearing.

Authority: T.C.A. § 68-11-1303.

1200-38-01-.05 Issuance and Maintenance of COPA.

- (1) After consultation with and agreement from the Attorney General, the Department shall issue a Certificate for a Cooperative Agreement if it determines the Applicants have demonstrated by clear and convincing evidence that the likely benefits resulting from the Cooperative Agreement outweigh any disadvantages attributable to a reduction in competition that may result from the Cooperative Agreement.
- (2) The Department shall grant or deny the Application within one hundred twenty (120) days of the date of filing of the Application. An Application shall not be deemed filed until the Application is complete. The Department shall act promptly to determine whether the Application is complete and may request additional documents or information from the Applicants necessary to make the Application complete. The Department's decision as to whether the Application should be granted or denied shall be in writing and set forth the basis for the decision. The Department shall furnish a copy of the decision to the Applicants, the Attorney General and any Intervenor. Prior to granting the COPA, the parties and Department will agree upon terms of certification and specific conditions that assure Public Advantage.
- (3) The Department shall maintain on file all effective COPAs.

Authority: T.C.A. §§ 68-11-1301 and 68-11-1303.

1200-38-01-.06 Active Supervision by Terms of Certification.

- (1) The Department shall maintain active supervision in accordance with the terms of certification described in 1200-38-01-.03. The Department shall not be bound by measures, indices or other conditions found outside of the COPA.
- (2) Periodic Reports. The Department shall maintain active supervision in addition to requesting COPA holders to submit periodic reports to the Department in a format determined by the Department. The periodic reports shall be filed with the Department on January 1 and July 1 (or the following business day) each year. The reports should include the name, address, telephone number and other contact information for the party responsible for completing future reports who may be contacted by the Department to monitor the implementation of the Cooperative Agreement.
- (3) Update Plan of Separation. The parties to the Cooperative Agreement shall update the parties' Plan of Separation annually and submit the updated Plan of Separation to the Department. The parties shall provide an independent opinion from a qualified organization which states the Plan of Separation can be operationally implemented without undue disruption to essential health services provided by the parties.
- (4) Modification of Index. The Department retains the right to modify any Measure, Index or condition under the COPA at any time.

- (5) The Department shall conduct a public hearing in the geographic service area where a COPA is in effect at least once every three (3) years.
- (6) Departmental Review. At least annually, the Department shall review such documents necessary to determine compliance with the terms of the COPA and calculate the Index. In addition to any required documents, the parties shall provide the Department with the most recent verifiable values available for those Measures that are included in the Index (except any Measures or factors which the Department itself regularly generates, receives or holds). The Department reserves the right to request supplemental information when needed, as determined by the Department.
- (7) Parties to the COPA must timely pay all applicable fees and invoices for initiation and maintenance of the COPA.
- (8) The Department shall make public its determinations of compliance, and the Index score and trends.
- (9) Failure to meet any of the terms of the COPA shall result in termination or modification of the COPA.

Authority: T.C.A. § 68-11-1303.

1200-38-01-.07 Modification/Termination.

- (1) If the Department determines that the benefits no longer outweigh the disadvantages by clear and convincing evidence, the Department may first seek modification of the Cooperative Agreement with the consent of the parties.
- (2) If modification is not obtained, the Department may terminate the COPA by written notice to the Certificate Holder and the Certificate Holder may appeal in the same manner as if the COPA were denied.
- (3) The COPA shall remain in effect until such time as the Certificate Holder has submitted, the Department has approved and the Certificate Holder has completed the Plan of Separation.
- (4) Voluntary Termination. The Certificate Holder shall notify the Department forty-five (45) days prior to voluntary termination of the Cooperative Agreement.

Authority: T.C.A. §§ 68-11-1303 and 68-11-1306.

1200-38-01-.08 Hearing and Appeals.

- (1) Applicant or Certificate Holder. Any Applicant or Certificate Holder aggrieved by a decision of the Department denying an Application, refusing to act on an Application or terminating a Certificate is entitled to judicial review of the Department's decision by the chancery court of Davidson County, as specified in T.C.A. 68-11-1303.
- (2) Intervenor. An Intervenor aggrieved by a decision of the Department to grant or deny the Application shall have the right to appeal the Department's decision, except that there shall be no stay of the Department's decision granting an Application unless the chancery court of Davidson County shall have issued a stay of the Department's decision in accordance with § 68-11-1304, which shall be accompanied by an appeal bond from the Intervenor. If the Intervenor shall appeal the Department's decision and the appeal is unsuccessful, the Intervenor shall be responsible for the costs of the appeal and attorneys' fees of the Applicants.

Authority: T.C.A. § 68-11-1303.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Health, Office of Health Planning (board/commission/other authority) on 09/24/2015 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/14/15 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 09/24/15 (mm/dd/yy)

Date: October 1, 2015

Signature: Malaka Watson

Name of Officer: Malaka Watson

Title of Officer: Assistant General Counsel
Department of Health



Subscribed and sworn to before me on: Oct. 1, 2015

Notary Public Signature: Luvemia Harrison

My commission expires on: Sept. 10, 2018

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

10/5/2015
Date

Department of State Use Only

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Filed with the Department of State on: 10-06-15

Effective on: 01-04-16

Tre Hargett
Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Hospital Cooperation Act of 1993 (COPA) Rulemaking Hearing September 24, 2015 Public Comments

Both oral and written comments were received for this rulemaking hearing. The oral comments will be addressed first.

The first oral comments came from Tom Lee with the law firm of Frost, Brown, Todd speaking on behalf of Amerigroup as its attorney. He stated that Amerigroup presently serves 400,000 Tennesseans through its role as a managed care organization contracting with TennCare. Mr. Lee thanked the Department for the work it has put in on this process already, and introduced Bob Leibenluft, with the Hogan Lovells Law Firm who has thirty-five years of experience as a health and antitrust lawyer, as well as experience with the FTC.

Mr. Leibenluft stated that as one of the largest purchasers of health care services in Tennessee, Amerigroup depends on competition among healthcare providers to contain healthcare costs, ensure quality, promote innovation, and offer alternatives to its members. He expressed concern over the rules, stating that without any adequate substitute for competition in Tennessee, granting state action immunity would harm the hundreds of thousands of Tennesseans whose care Amerigroup coordinates. He went on to state that the granting of state action immunity is rare; just four states have considered it and one of those states, North Carolina, is considering revoking it. He stated several reasons why state action immunity is unusual. First, he said that we rely on competition within the healthcare market to incentivize hospitals to keep their costs low, not to raise prices, to keep quality high, to acquire the latest technologies, to provide convenient access, to attract the best employees, and to provide the level of amenities and services that will satisfy their customers. Secondly, he stated that it is impossible to substitute regulatory oversight for competition. Third, he said regulatory oversight must be ongoing and dynamic. Fourth, he said healthcare providers do not need to merge to achieve efficiencies. They can achieve better quality and lower costs on their own. And as the FTC has pointed out on numerous occasions, there are many ways that healthcare systems can collaborate with each other which does not raise the competitive concerns of a merger. Fifth, he said once a merger is approved under state action immunity, it is difficult to undo. Lastly, he said the law, including two very recent Supreme Court cases, sets a very high bar for private parties to obtain state action antitrust immunity. The high bar imposes very stringent requirements on the State not only to articulate clearly its intent to displace competition, but also with respect to how the legislation has been enacted to provide active and ongoing supervision over anticompetitive conduct. He went on to state that for these reasons, the regulation under consideration governing the process for seeking a COPA and the oversight that will be applied if a COPA is granted are critically important and that the Department must ensure that the COPA applicant clearly describe the following: 1) what they intend to achieve through the COPA; and 2) why these goals could not be achieved without COPA: what benefits they think will likely be achieved through the COPA, how these benefits can be measured, what the likely adverse effects of the COPA are, and what commitments the applicants are willing to make to protect consumers from these adverse effects. Mr. Leibenluft added that the hospitals can certainly talk about what they plan to do if they were to merge or if they were to combine. Once they combine they can talk about the merger in this kind of context; if they are seeking this kind of antitrust exemption they should be required to explain exactly what they're going to be doing. He also states that the process must provide for a transparent process so the public has a full opportunity to understand and provide input and that the applicants have the burden of proving by clear and convincing evidence, that is a high standard, that the advantages of a COPA outweigh the disadvantages.

He stated that Amerigroup believes the proposed regulations make considerable progress towards achieving these goals and commended the Department for the hard work in the drafting process, but stated that Amerigroup feels there are several ways the regulations can be improved. He urged that the proposed regulations not be scaled back and include requiring detailed information in the initial application, such as the creation of an advisory

group to provide input to track the performance under the COPA, and full funding by the applicants of the cost of the review of the application and any ongoing monitoring; emphasizing that review really has to be almost like a public service commission review of a utility. It has to be ongoing, involving staff, involving expertise. He urged for a plan of separation to be required that would show how competition will be restored in the event a COPA must be terminated. Amerigroup urges the inclusion of the following in the application review process: 1) information describing each proposed benefit under the COPA: why the benefit can't be achieved without anti-trust immunity, what metrics should be used in determining whether the benefit is being achieved, and what commitments, if any, the applicant is willing to make; 2) it should be explicit that the Department may impose certain conditions in a COPA including price caps; and 3) expanding the role of the advisory group. But Amerigroup thinks input from stakeholders and other experts are needed, not only to do that initial review but also to provide that ongoing supervision of the applicants if the COPA is granted. He closed by stating that Amerigroup has also submitted written comments including a redline for consideration and said he appreciated this opportunity to provide input to the Department on these very important regulations.

The next comments came from Highland Physicians (Holly McDaniel and Brant Kelch). Mr. Kelch stated that Highland Physicians is an Independent Practice Association and has been serving the same geographic area as the hospitals that may seek a COPA and, as such, the practice will be affected by these rules. He explained that the practice had over one thousand physicians with a diversity of opinions as to the statutes/rules regarding the COPA program. He stated that typically monopolies are not good unless you are one, but that he believes that that this could be a good one for the community if done correctly. He closed by thanking the Department for its work and by drawing attention to the written comments of the physicians in the practice and stated that they were both impressed and encouraged by the rules and know that the Department is committed to making sure that this is going to be done right and done right initially, but to continue monitoring. He stated the practice totally supports that.

The next commenter was Jeff Merrill, a family physician, with Mountain States Health Alliance. He stated that he has worked in the tri-cities for nineteen years and is the medical director of Clinical Transformation from Mountains States Medical Group, which is a specialty medical group comprised of over three hundred providers in over one hundred locations in northeast Tennessee and southwest Virginia. Additionally, he stated he serves on the new care collaborative board, which is the accountable care organization for Mountain States Medical Group, and he also serves on the TennCare Patients In Home Technical Advisory Group. He went on to state that there are many challenges facing the geographic region such as very high rates of obesity, mental illness, substance abuse, bacterial pneumonia, chronic diseases such as diabetes and heart disease, and that the region needs a new approach to address these problems in the region. He said the COPA legislation provides for a local solution to these problems, and that the merger of Mountain States Health Alliance and Wellmont Health Systems would allow this new organization to utilize more efficiently the limited resources to build an infrastructure that is needed to deliver affordable accessible population-based healthcare at the highest quality to people in our region, all of which aligns with the State of Tennessee's goals – to move from volume to value-based healthcare for the people of Tennessee. He closed by stating that the rules are important because they provide State oversight of the proposed new organization, and that he certainly welcomes and encourages that oversight. He thanked the Department for its work to develop rules that are both firm but also provide the new organization to be flexible. He stated the rules will allow the new organization to work and develop innovative solutions to the many healthcare challenges that face the region.

The next comment came from Greg Neil, Wellmont, CEO of Bristol Regional Medical Center. He stated that Bristol Regional serves Northeast Tennessee and Southwest Virginia including thousands each year. He stated that the ability for Bristol Regional to continue in its important mission to deliver superior healthcare with compassion is vital to ensuring the future of healthcare in upper east Tennessee and southwest Virginia. He further stated that he cares about the rules not only because they will provide the framework for the entities wishing to come together under a cooperative agreement, but also because they are integral to the proposed consolidation between Mountain States Health Alliance and Wellmont Health System. Our two organizations propose to come together to improve the healthcare of folks in our area. The overriding purpose of what is contemplated is to provide the absolute best care possible at the most affordable cost. He also stated that both organizations are indeed committed to open dialogue and engaging with the public; the organizations respect the spirit of transparency that's found in the legislation and have shown their commitment to that through an unprecedented number of public meetings and open dialogue. He said that the two organizations are working with East Tennessee State University through several focused community work groups to learn even more about what the communities in the region feel are important focus points for the future of healthcare and health status improvement in the area. He closed by stating the proposed merger will provide a locally governed solution to

the rapidly changing healthcare environment and that the two organizations believe a local solution is the best one for the future, and the Tennessee COPA Law provides that solution to become reality. He said he would let his written comments stand and thanked the Department personally for the opportunity to speak and especially for its hard work.

The next commenter was Lindy White, a CEO of two community hospitals in East Tennessee with Mountain States Health Alliance, one being an eighty bed acute care facility and one being an eighty-four bed psychiatric inpatient hospital. She first thanked the Department for its work on the rules, which she said were an innovative approach to look at how they might ultimately improve her region's health outcomes and access, and population health improvement, while simultaneously reducing costs and providing value for our patients. She stated that she has been in the trenches as a CEO in rural community hospitals for the last nine years and clearly understands the challenges that the region has aggressively faced. As reimbursements have declined and costs continue to increase, the supply of nurses and physicians continue to decline causing some of those costs to push forward. Hospital operators have to deliver care that is more efficient and more effective at reducing mortality and reducing hospital infections. She stated that this legislation and the proposed merger of the two healthcare systems will allow those decisions to be kept locally. They are pretty important decisions in regards to where we offer services, how our patients access those services and how we improve the preventative care that is needed in our communities as well as the quality. She further stated that those of us that live alongside our neighbors are in the best place to make this determination and that to have the opportunity to do so collectively, as two hospital systems, is truly one of the advantages of the legislation. She went on to say a second advantage of the legislation is that we can work together collaboratively to improve processes, continually improving processes and outcomes for our patients and do so extremely well. She closed by stating that she is really excited about the work that can come from this proposed merger, the ultimate outcome, and that one of the biggest beneficiaries from this could be the improvements and the access to behavioral health and mental health services in the region. She said this legislation could improve access to outpatient services and access to residential homes. She thanked the Department and legislature for their hard work and encouraged that the rules be flexible and that the systems welcomed Departmental oversight from the State's perspective because the systems truly believe that the benefits outweigh the disadvantages.

Alice Pope, the executive vice president and chief financial officer for Wellmont Health Systems, was the next commenter to speak. She stated that she has served Wellmont Health Systems for over 15 years and is a resident of East Tennessee. She also stated that current Tennessee law governing the type of proposed mergers such as the one contemplated by Wellmont Health Systems and Mountain States Health Alliance provides important State oversight capabilities as codified in many other states and affirmed by the United States Supreme Court; it is well regarded as providing the ability of states to regulate particular kinds of agreements where they will benefit the people we serve. She said that it is particularly important to note that the statute put in place provides the ability for the State to work to ensure that care remains affordable, that a broad array of healthcare choices be available to patients, and that access to that care is ensured and even expanded. She further stated that these are the goals of the proposed merger between Mountain States and Wellmont. She said the statute provides for a level of consumer protection that would not be available otherwise and provides an avenue for Mountain States and Wellmont to come together and ensure that a local solution is available for the future of healthcare in our region which is welcomed because out-of-market mergers result in increased healthcare costs and do not protect the consumer. She went on to state that people are mistakenly referring to out-of-market mergers when pointing to the high costs associated with mergers. She said that the oversight of the COPA will ensure that consumers are protected and costs are controlled. Lastly, she stated while others have shared that the expense of the COPA and additional government oversight is not necessary, that it is probably too late for that because seventy percent of the business is Medicare and Medicaid, so government oversight and regulations is something that we deal with every day, and we are accustomed to it and we do it very well. She closed by thanking the Department for its time and stated that Wellmont appreciates everything that is being done.

Dick Lodge, an attorney for Mountain States Health Alliance with Bass, Berry, and Sims, addressed the Board and stated that he would rely on his written comments as part of the record.

The next commenter was Paige Kisber with the Hospital Alliance of Tennessee who commented on the rules from a state-wide perspective. She stated that these rules are important because they will apply to a law that is critical for the future of local not-for-profit healthcare in upper East Tennessee and provide the opportunity for two organizations, Wellmont Health Systems and Mountain States Health Alliance, to come together to ensure a locally controlled and locally governed solution for that part of the state and to serve tens of thousands of Tennesseans while dedicated to affordability and access. She stated that by combining resources and leveraging

them, these two organizations can work as a new entity under the state law and under proper state supervision toward providing top quality healthcare that is accessible and affordable. This is a unique opportunity that cannot be passed up. She encouraged the Department to develop rules that provide the best regulations in a framework that is flexible enough to allow the proposed new organization to develop innovative healthcare solutions for the people in that part of the state. She closed by stating that she believes this structure, if approved, would uniquely position these hospital providers to be leaders in our state in helping our state to reach its population health policy goals which is good for the whole state and she thanked the Department for the work it is doing.

The next commenter was Tom Allen, General Counsel for Mountain States Health Alliance. He opened by stating that he appreciated the opportunity to come and speak and stated that the rules are lucid and understandable, and that he only has comments from a legal standpoint on two of the matters in the rules. First, he said is the requirement that a Plan of Separation be filed with the application for a Certificate of Public Advantage which the statute does not require be filed and that such requirement presents some very real logistical and planning difficulties for the organizations. Secondly, he said is the requirement of the submission of confidential, competitive information that would be disclosed to the public which would create some serious conflict with long standing principles of federal law and also just generally with other competitors that might be in the market. He also stated that the purpose of the proposed merger is to keep a local solution to high quality healthcare available, widely accessible, and affordable for the people of our region because thousands of Tennesseans whom are served by the hospital systems deserve locally governed and locally controlled healthcare options. He closed by stating that he additionally submitted written comments and that the State's policy in favor of supplanting competition is clearly articulated in the statute and that the regulations that provide for ample and rigorous active supervision by the State and thanked the Department for its efforts in developing flexible but firm rules that will allow for solid oversight to keep healthcare affordable and available to the highest quality possible for the residents of Northeast Tennessee and the entire state. He said it is vital to the people of our region and for the State of Tennessee to continue on this path to ensuring the proposed merger can move forward in a way that preserves local control over healthcare in upper East Tennessee.

Stephanie Wilkins, an attorney advisor in the Federal Trade's Commission Office of Policy Planning, next addressed the Department. She opened with a disclaimer stating that the oral remarks were her own based on the views of FTC staff and did not necessarily represent the views of the commission or of any individual commissioner, but that the Commission voted to authorize her to appear and voted to authorize staff to submit written comments. She stated that FTC staff has significant expertise in the evaluation of hospital mergers, including assessing whether a potential benefit for the transaction outweighs the potential and competitive harms. She stated that the benefits and disadvantages that the Tennessee Department of Health must consider are among the very factors that the FTC considers when evaluating a hospital merger. She further stated that the FTC devotes considerable resources to gather sufficient data and conduct detailed analysis to understand the likely competitive effects of hospital mergers. She said that, in their experience, mergers between close competitors and highly concentrated healthcare provider markets are more likely to result in significant consumer harm than a merger in a less concentrated market which she said is supported by numerous studies and comparable research. She said that, as a result, the potential benefits and efficiencies must be greater and more likely to be passed through to consumers to offset the likely anti-competitive harms and disadvantages, and that the FTC has consistently advocated that legislation purporting to grant anti-trust immunity is unnecessary to encourage co-competitive collaboration among healthcare providers which is likely to undermine the laudable public policy goal of improving quality, reducing costs, and improving patient access for healthcare services. Consequently, she said, the FTC urges the Department of Health to be diligent in evaluating the potential competitive effects of COPA applications. She also stated that FTC staff is willing to provide any expertise and information that it is authorized to share in connection with review of COPA applications, and that FTC Staff investigations may benefit from receiving this information and materials submitted as part of any COPA application that the Tennessee Attorney General's Office and the Tennessee Department of Health are able to share with it. She closed by urging that these concepts of permissible sharing of information and expertise between the Tennessee Department of Health, the Tennessee Attorney General's Office, and the FTC, be incorporated in the promulgated rules.

The next commenter was Bridget Baird with East Tennessee State University (ETSU). She first thanked the Department for allowing her to speak. She stated that people in the region face many healthcare challenges and that the COPA law would help address them in a very innovative way by providing for State oversight of the proposed merger between Wellmont Health Systems and Mountain States Health Alliance. She said that the rules would keep the organization local, which ETSU supports. She said ETSU believes the proposed new organization would positively impact East Tennessee State University and give it an opportunity to further

advance clinical education in the region which would allow it to be more competitive in pursuing research dollars currently flowing elsewhere nationally. She stated that the President of ETSU would also serve as a member of this new system board. She stated that both Mountain States and Wellmont have been forced to reduce residency positions in recent years and that this partnership would allow them to reverse that trend. She said the new organization would also partner with ETSU and others to strengthen the pipeline of physicians and allied health professionals, and attract research jobs and investments in our region, and that ETSU would help conduct a substantial comprehensive regional health care assessment which would address health gaps and disparities which would help change the future direction of the potential new system and establish its priorities. She closed by stating that these are all very important reasons why the rules are so critical and commended the Department on its efforts and hard work. She said that ETSU looks forward to working with this new organization to make the healthcare needs in our region the best possible for our constituents and our folks that live in the area.

The last comment came from Chris Puri with America's Health Insurance Plans. He stated that to the extent that the written comments would become part of the record that America's Health Insurance Plans would just rely on the written comments that were previously submitted.

The following chart represents the written comments.

ORGANIZATION	GENERAL DISPOSITION	SPECIFIC COMMENTS
<p>America's Health Insurance Plan</p>	<p>Opposes the granting of a COPA because it is impossible to provide oversight that can fully substitute competition.</p> <p>Although TN has adopted a statute, concerns are relevant as the state adopts regulations and considers applications under those regulations.</p> <p>Cites Supreme Court cases North Carolina State Board of Dental Examiners v. FTC and FTC v Phoebe Putney Health System to support opinions.</p>	<p>Supreme Court has made it clear that state action immunity is disfavored and therefore available to private parties in only narrow circumstances.</p> <p>FTC has advised that COPAs are both unnecessary and are instead likely to lead to "increased health care costs and decreased access to health services."</p> <p>Respectfully suggests that the FTC guidance, the difficulty, cost, and uncertainty of obtaining state action immunity, and the record of consumer harm from anticompetitive hospital consolidation be weighed significantly in consideration of regulations and applications.</p> <p>Contends the best approach is to prevent anticompetitive mergers and preserve competition in TN.</p>
<p>Federal Trade Commission Staff</p>	<p>Emphasizes previous concerns regarding COPA programs and other antitrust exemptions.</p> <p>The FTC has consistently advocated that legislation purporting to grant antitrust immunity is unnecessary to encourage procompetitive collaborations among health care providers. Antitrust laws are consistent with public policy goals.</p> <p>Nevertheless, the FTC recognizes the Department must promulgate rules to implement TN's amended hospital corporation legislation.</p>	<p>FTC has significant expertise in evaluating proposed hospital and other health care provider mergers, including assessing whether the potential benefits of a transaction outweigh the potential anticompetitive harm.</p> <p>FTC devotes considerable resources to gather sufficient data and conduct detailed analyses to fully understand the likely competitive effects of all mergers.</p> <p>Requests the concepts of permissible sharing between the FTC, TN Attorney General, and TN Department of Health be incorporated in the promulgated rules.</p>

<p>Amerigroup (wholly owned subsidiary of Anthem)</p> <p><i>Amerigroup is a provider of health insurance for individuals and groups eligible for coverage under Medicare Advantage (HMO) and Medicaid in Tennessee.</i></p>	<p>Provides background on antitrust immunity under the state action doctrine, describes the legal test under which grants of immunity have been challenged by courts, provides recommendations regarding the state's role in actively supervising a COPA, including the process for evaluating a COPA application, obligations for applicants related to rate-setting in health plan contracts, and obligations for applicants related to quality measures.</p> <p>Provides an overview of Amerigroup's recommendation for how the Department should approach its obligations in assessing COPA applications and overseeing conduct subject to a COPA, and concludes with specific comments to the Proposed Regulations.</p>	<p>Keep letter of intent 45 day requirement.</p> <p>Require additional information in the Application including:</p> <ol style="list-style-type: none"> 1. More specific information on the market and market dynamics. 2. A detailed description of each benefit that the applicants propose will be achieved through the Cooperative Agreement. 3. Request a description of any commitments the applicants are willing to make to address any potential adverse impacts resulting from the Cooperative Agreement. <p>Require a description of the market and the competitive dynamics for health care services in the applicants' respective service areas.</p> <p>Delete the waiver provision for certain Application requirements</p> <p>Specify that the Department may impose certain conditions in a COPA and in particular pricing caps.</p> <p>Include a waiver of statute of limitations for antitrust challenges brought post-separation.</p> <p>Expand the role of the advisory group to provide support to the Department in performing ongoing supervision.</p>
<p>Wellmont Health System and Mountain State Alliance</p>	<p>Comments from a legal standpoint only.</p>	<p>A plan of separation is not required by the statute to be filed with the application for a certificate of public advantage. Requests that the plan of separation not be required with the application. If the Department deems the inclusion necessary, the rules should clarify that any plan of separation can be stated in general terms of processes and structure.</p> <p>The joint submission and public disclosure of competitively sensitive information required by the proposed rules conflicts with federal antitrust law and subjects the parties to potential antitrust liability. The parties respectfully request the rules be modified to address this significant federal law issue. The parties cite the Sherman Act, which prohibits anticompetitive collusion between competitors.</p>

<p>BlueCross BlueShield of Tennessee, Inc.</p>		<p>Reword 1200-38-01-.03(2) as follows: "Evaluation of the Application by the Department that..."</p> <p>Expand the role of the advisory group to assist in analyzing whether the issuance of a COPA should occur.</p> <p>Reorder sections in rules to follow the sequential order of intention of the regulations.</p>
<p>Highland Physicians, Inc.</p> <p><i>Highland Physicians is a clinically integrated independent physician association using a collaborative model to provide coordinated medical care to the residents of Northeast Tennessee and Southwest Virginia.</i></p>	<p>Wants to make certain the transaction is structured and monitored to guarantee fair and balanced competition among all providers in the affected region.</p> <p>If hospital competition in TN is reduced or eliminated through corporate combination of Wellmont and Mountain State, it is essential that regulations protect the community from potential adverse effects. Strongly recommend creating a regulatory environment that continues to encourage and protect competition to improve efficiency and quality care.</p>	<p>1200-38-01-.01 - Modify the definition of Hospital to reflect the breadth of services offered or controlled by most hospitals and medical centers. Add a new defined term entitled "Independent Physician."</p> <p>Expand on potential disadvantages at 1200-38-01-.02(2)(a)3 by including: closure or consolidation of programs and facilities, and the potential impact on access to services; reducing selected administrative and clinical functions and loss of jobs; narrowing of traditional payer networks leading to reduction of patient choice in choosing physicians and services; and negative impact on Independent Physicians due to the anticipated increase market concentration in physician and medical services controlled by the Applicants.</p> <p>Asserts 1200-38-01-.02(2)(a)9 is one of the most critical components of the entire Application. Recommends the regulatory text ask for explanations as to how the Cooperative Agreement will ensure continued competitive and independent operation for specific stakeholder groups potentially impacted by the merger. The explanation should reference specific policies, initiatives and commitments contained in the Cooperative Agreement that support the explanation for each stakeholder group- including a commitment not to use Certificates of Need requirements to oppose development of new ambulatory facilities by entities not a party to the Cooperative Agreement.</p> <p>Amend 1200-38-01-.02(2)(a)9 by asking Applicants to declare their intentions regarding future employment of physicians in the region.</p> <p>Expand 1200-38-01-.02(2)(a)12 by requiring the Parties to submit a summary of public campaign and communication efforts to maximize community awareness and participation in the educational processes.</p> <p>1200-38-01-.02(2)(a)13(v) – One of the cornerstones of the application. Enhance to require the Parties to include with submission of their independent, expert opinion that the</p>

		<p>information provided is accurate and complete, and the potential competitive impact is through, and objective.</p> <p>1200-38-01-.02(2)(a)13(v)- Require Applicants to describe how the financial advantages of Cooperative Agreement – particularly as it relates to potential bonuses associated with at-risk accountable care arrangements or performance incentives tied to specific payer contracts- are shared with their employed contracted physicians.</p> <p>1200-38-01-.02(2)(a)13(vii) - Amend the clinical integration plan to include Independent Physicians and other providers in the service area.</p> <p>1200-38-01-.02(2)(a)13(x) - Expand measures to include elements that reflect both the anticipated advantages and disadvantages.</p> <p>Amend 1200-38-01-.03 (3)(b) to include advantages and disadvantages.</p> <p>Amend 1200-38-01-.03 (3)(e) to include at least one independent physician on the advisory group.</p> <p>1200-38-01-.04(1)- Increase the number of Department held public hearings held prior to acting on an application to two (2) in the geographic service area.</p> <p>1200-38-01-.06- Increase the number and frequency of Department held public hearings after granting a COPA to annually for at least the first four (4) years, then at least biannually for the next four (4) years, after which holding a public hearing at least every three (3) years.</p> <p>1200-38-01-.08(2) - Reconsider the appeals process for Intervenors aggrieved by a decision to grant or deny a COPA to ensure it is not onerous, as to discourage those with substantive objections.</p>
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The Department did not incorporate changes suggested by the comments, but adopted the rules as originally proposed. The Department may seek to amend the rules based upon the comments after the new chapter is effective.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

REGULATORY FLEXIBILITY ANALYSIS

- (1) **The extent to which the rule or rules may overlap, duplicate or conflict with other federal, state and local governmental rules.**

These rules do not overlap, duplicate or conflict with other federal, state and local government rules.

- (2) **Clarity, conciseness and lack of ambiguity in the rule or rules.**

These rules are established with clarity, conciseness and lack of ambiguity.

- (3) **The establishment of flexible compliance and/or reporting requirements for small businesses.**

These rules do not contain compliance and/or reporting requirements for small businesses.

- (4) **The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.**

These rules do not contain compliance and/or reporting requirements for small businesses.

- (5) **The consolidation or simplification of compliance or reporting requirements for small businesses.**

These rules do not compliance and/or reporting requirements for small businesses.

- (6) **The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.**

These rules do not establish performance, design or operational standards for small businesses.

- (7) **The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation or increase costs.**

These rules do not create unnecessary barriers or other effects that stifle entrepreneurial activity, curb innovation or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Division of Health Planning, Certificate of Public Advantage (COPA)

- 1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

Any impact upon small businesses flows from the Hospital Cooperation Act of 1993 which authorizes the proposed rules. The Act implicitly recognizes that the hospitals are entering into a cooperative agreement to share assets and in some cases completely merge their assets. To the extent the transaction affects the market of the region served by the hospitals, there may be some effect on small businesses; however, the extent to which this may occur is unknown.

- 2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

The parties to the cooperative agreement will submit an application and reports concerning all aspects of their service. These reports will require varying levels of skill, including economic experts, population health experts, executive leadership expertise, and financial reporting experts.

- 3. Statement of the probable effect on impacted small businesses and consumers:**

See answer to question 1 above.

- 4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business: N/A**

- 5. Comparison of the proposed rule with any federal or state counterparts:**

Federal: N/A

State: Rules are established in states with similar enabling legislation. During the drafting process, the rules were compared to rules regulating cooperative agreements in Maine, New York, Montana, and North Carolina. The rules in all states noted above aim to set forth active state supervision, as required under *FTC v. Phoebe Putney Health System, Inc.*, 133 S. Ct. 1003.

- 6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

N/A

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The rules in this chapter implement the law relative to Cooperative Agreements and the granting of Certificates of Public Advantage pursuant to the Hospital Cooperation Act of 1993, T.C.A. §§ 68-11-1301 through 68-11-1309.

Pursuant to the Act, the Department is responsible for active state supervision to protect the public interest and to assure the reduction in competition of health care and related services continues to be outweighed by clear and convincing evidence of the likely benefits of the cooperative agreement, including but not limited to improvements to population health, access to services and economic advantages to the public. A Certificate will be denied or terminated if the likely benefits of the cooperative agreement fail to outweigh any disadvantages attributable to a potential reduction in competition resulting from the cooperative agreement by clear and convincing evidence.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. 68-11-1307 (d) authorizes the Department of Health to promulgate rules to implement the Hospital Corporation Act of 1993.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Entities most affected include hospitals, providers, payers, consumers, and parties of a cooperative agreement.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

FTC v. Phoebe Putney Health System, Inc., 133 S. Ct. 1003.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

These rules do not impact government revenues and expenditures. All costs associated with the implementation and ongoing supervision flow from the Hospital Cooperation Act of 1993. Pursuant to the statute, the parties to a Cooperative Agreement are responsible for the costs of the Department, including the cost for consultants.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Malaka Watson, Assistant General Counsel, Department of Health.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Malaka Watson, Assistant General Counsel, Department of Health.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel, Department of Health, 710 James Robertson Parkway, 5th Floor, Nashville, TN,
(615) 532-7173, Malaka.Watson@tn.gov.

(l) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.