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Emergency Rule Filing Form

Emergency rules are effective from date of filing for a period of up to 180 days.

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Rule Type:

Emergency Rule

Revision Type (check all that apply):

Amendment

New

Repeal

Statement of Necessity:

The Hospital Cooperation Act of 1993, Tenn. Code Ann. § 68-11-1301 – § 68-11-1309 was amended by the General Assembly on May 18, 2015, 2015 Tenn. Pub. Acts, ch. 464. The original legislation provided that hospitals could enter into a "cooperative agreement" for the sharing or referral of personnel, patients and assets. The parties to the cooperative agreement could apply to the Department of Health ("department") for a certificate of public advantage governing the cooperative agreement. After consultation with and agreement from the attorney general, the department was required to issue the certificate of public advantage if it determined that the applicants had demonstrated by clear and convincing evidence that the likely benefits from the agreement outweighed any disadvantages attributable to a reduction in competition.

The 2015 legislation made significant changes to this Act. The Act now provides that a cooperative agreement among hospitals may include consolidation by merger or other combination of assets. The Act also now includes a statement that "[i]t is the policy of this state, in certain instances, to displace competition among hospitals with regulation," and specifically requires that there be active supervision of such cooperative agreements in order to provide state action immunity from federal and state antitrust law to the fullest extent possible. Among the benefits that must result from the cooperative agreement are enhancement of the quality of hospital care, demonstration of population health improvement of the region served according to criteria approved by the department, and the extent to which medically underserved populations have access to and are projected to utilize the proposed services. The 2015 Act also changed the enumeration of benefits that the parties are required to demonstrate and provides a different procedure for appeal and review of a decision denying or terminating a certificate of public advantage. These amendments to the Hospital Cooperation Act allowing for the consolidation by merger of hospital entities went into effect immediately upon becoming law.

The Department has received notice from two hospital entities that they propose to merge and to apply for a Certificate of Public Advantage under the amendments to the Act within the next several months. The proposed merger of the two hospital entities will result in the consolidation not only of the assets of these two entities, but also a consolidation of the services and products and service locations of these two entities, including but not limited to hospitals, inpatient facilities, insurance products, physician practices, pharmacies, accountable care

organizations, psychiatric facilities, nursing homes, rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer center or services, imaging centers or services, and support services. Clearly, such a merger will have a significant effect on the public health and safety of the citizens located in the geographic service areas of these two hospital entities.

The Commissioner of Health ("Commissioner") is authorized pursuant to Tenn. Code Ann. § 4-5-208 to promulgate emergency rules in the event of an immediate danger to the public health, safety or welfare. Because of the significant changes to the Hospital Cooperation Act allowing the consolidation of hospital entities and because of the imminent filing of an application for a certificate of public advantage, emergency rules governing the application process, the approval process, including the measures for determining whether the likely benefits of the proposed merger will outweigh any disadvantages resulting from a reduction in competition, are necessary in order to ensure that the public health, safety and welfare of the citizens are adequately protected. The Commissioner believes that it is not possible to promulgate either rulemaking hearing rules or publication rules in time to provide the necessary guidance to sufficiently review the proposed merger of the two hospital entities and application for Certificate of Public Advantage, which is imminent. This inability to conduct a sufficient review presents an immediate danger to the public health, safety and welfare of the citizens located in the geographic service areas of these two hospital entities. Thus, these emergency rules are necessary to provide the Department with the sufficient guidance to be able to adequately and appropriately review the proposed merger and application in order to protect the public health, safety and welfare.

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/RuleTitle 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, a hospital, 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 with the Department.
 - (a) Contents. A letter of intent shall contain 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 affiliated 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 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 is filed with the Department within that period.
- (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 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;
 - (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 individual or entity under the

Cooperative Agreement including the amount, nature, source and recipient;

- (ii) 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;
- (iii) A list of all services and products and of 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) 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;
 - (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 a 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 to 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 the uninsured and indigent,
 - C. Policies for bad debt write-off; and
 - D. Policies that assure parties to the Cooperative Agreement will maintain or exceed the 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 to the Cooperative Agreement, in the proposed geographic service area, that addresses the following:
 - (I) A streamlined management structure, including 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 assumptions 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 operating 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 designed 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 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, costs for consultant 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 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 and the Attorney General are vested 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. The charges shall include all expenses of the Department, including, but not limited to, the fees and expenses of experts and examiners employed in the review and ongoing supervision of the Application and COPA.
 - (b) The charges assessed by the Department, and the fees and expenses of experts and examiners contracted by the Commissioner to examine and review 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.
 - (d) The obligation to pay charges assessed under this section shall be the joint and several obligation of the parties to the Cooperative Agreement.
- (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 by 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. The advantage is clear and convincing, in which event the COPA will continue in effect,
2. The advantage is not clear and convincing in which event a modification to the Cooperative Agreement under the terms of certification will be necessary,
3. The advantage is not evident, in which event COPA will be terminated in accordance with 1200-38-01-.07.

(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, affiliates, contractors or vendors, staff clinicians and 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, and 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, 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 with, 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 T.C.A., 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 forty-five (45) days prior to the date set for the public hearing and shall be deemed given five (5) business days from the date notice was transmitted to the secretary of state for publication.

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 after 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 whether the Application should be granted or denied shall be in writing and shall 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 the 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. § 68-11-1303 and 68-11-1.

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 shall 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 may 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 Cooperative Agreement 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 at least 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 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 an emergency rule(s), lawfully promulgated and adopted.

Date: July 14, 2015

Signature: Malaka Watson

Name of Officer: Malaka Watson

Assistant General Counsel

Title of Officer: Department of Health



Subscribed and sworn to before me on: 7/14/2015

Notary Public Signature: Luvenia Harrison

My commission expires on: September 10, 2018

All emergency 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
7/14/2015
 Date

Department of State Use Only

Filed with the Department of State on: 7/14/15

Effective for: 180 *days

Effective through: 11/10/16

* Emergency rule(s) may be effective for up to 180 days from the date of filing.

Tre Hargett

Tre Hargett
Secretary of State

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 PUBLICATIONS

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.

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

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, SS-7040 (November 2014)

(615) 532-7173, Malaka.Watson@tn.gov.

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

None.