

**DEFICIENCIES OF THE PROPOSED
CON NONSUBSTANTIVE REVIEW REGULATION, 900 KAR 6:075**

The Cabinet for Health and Family Services (“Cabinet”) has proposed a new version of the CON Nonsubstantive Review Regulation, 900 KAR 6:075, which includes a Special Exception to the longstanding rule that CON applications to establish Class I ground ambulance services (911 scene/first responder) are subject to formal review. The Special Exception allows CON applicants in only three of Kentucky’s 120 counties, McCracken, Laurel, and Warren, to have their CON applications reviewed under the deferential nonsubstantive review standard rather than formal review. This Special Exception makes the proposed 900 KAR 6:075 deficient under KRS 13A.030(2)(a) for the following reasons:

(1) The Regulation is wrongfully promulgated because it is special legislation.

- Sections 59 and 60 of the Kentucky Constitution prohibits favoritism by the legislature or state agencies towards an individual or small group.
- The Statement of Consideration shows that the Special Exception was the result of clear favoritism by the Cabinet towards TriStar Greenview Regional Hospital, which is seeking a CON for a Class I ground ambulance service in Warren County.
- At page 37 of the Statement of Consideration, the Cabinet states that it amended the proposed 900 KAR 6:075 as requested in comments submitted by TriStar Greenview Regional Hospital because an independent administrative hearing officer ruled that Greenview’s CON application was not entitled to nonsubstantive review.
- The Cabinet further explains at page 22 of the Statement of Consideration that “[w]hile the amendment to 900 KAR 6:075 does not guarantee that TriStar Greenview Regional Hospital will obtain a certificate of need to serve Warren County, it does remove one of the barriers”
- The Constitution does not permit this favoritism, which the Statement of Consideration shows to be the express purpose of the Special Exception.

(2) The Regulation exceeds the Cabinet’s authority.

- Under the Doctrine of Separation of Powers in the Kentucky Constitution, regulations must reflect administrative rather than policy decisions because policy considerations are exclusively the prerogative of the legislature.
- The purpose of the Special Exception is to impermissibly further the policy objective of the Cabinet to increase the number of ambulance providers, specifically in Warren County.
- It is the prerogative of the legislature rather than the Cabinet to determine policy related to ambulance providers.

(3) The Regulation impermissibly conflicts with KRS 216B.010.

- A regulation is invalid if it conflicts with the purpose of a statute.
- KRS 216B.010 gives three purposes for the CON program: (1) to prevent proliferation of unnecessary healthcare facilities and services; (2) to prevent costly duplication of healthcare services; and (3) to create a cost-efficient healthcare delivery system.
- The Special Exception’s explicit purpose to promote the duplication of ambulance providers in Warren County is directly contrary to the General Assembly’s stated purposes for the CON program.

STATEMENT OF CONSIDERATION RELATING TO
900 KAR 6:075

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Certificate of Need

Amended After Comments

I. A public hearing on 900 KAR 6:075 was held on November 26, 2018, at 9:00 a.m. in the Health Services Building, 275 East Main Street, Frankfort, Kentucky. Additionally, written comments were received during the public comment period.

II. The following people submitted comments during the public hearing or public comment period:

<u>Name</u>	<u>Agency/Organization/Other</u>
Ghayth Hammad, MD	Ghayth Hammad, M.D., P.S.C. Internal Medicine, Morgantown, Kentucky
Sheila Kennedy	Citizen, Logan County
Hugh C. Runner	Bowling Green community member
Jeffrey S. Joyce	Bowling Green community member
Mac Jefferson	Bowling Green community member
Sarah C. Moore	Bowling Green community member
DC Clement	State Farm Insurance Agent, Bowling Green
Thomas M. Loving	Director, Bowling Green Warren County Drug Task Force
Anonymous	Anonymous
Shawn Alcott; Craig Beard, MD; Joe Gass, MD; Jack Glasser, MD; John Gover, MD; Greg Malmquist, MD; Alan Palmer; Heather Rogers; Mike Sherrod	TriStar Greenview, Board of Directors
Kamal P. Singh, MD	Graves Gilbert Clinic, Board of Directors
Avinash Aravantagi, MD	Graves Gilbert Clinic
Douglas B. Thomson, M.D., M.P.H.	Graves Gilbert Clinic
Faith Sun, MD	Graves Gilbert Clinic
John Ruth, MD	Graves Gilbert Clinic
Judy Waddell, APRN	Graves Gilbert Clinic

who were not transported by the Medical Center EMS, over 60% choose to go to Greenview.

Attached as Exhibit 2 are approximately 60 letters of support for the Mikrod CON application. Several of these attest to the Medical Center EMS practices with regard to transports to its own hospital, including implicit and explicit coercion of patients and families as well as overt refusal to honor requests to go to Greenview.

Thank you for the opportunity to comment on the proposed revisions in this regulation. We will be happy to provide additional information or follow up if you desire."

(b) Response: Thank you for your comments in support of the amendment. Since the General Assembly authorized the Cabinet to administer the certificate of need program and implement health policy for the Commonwealth, the Cabinet has been attentive to the supply and demands of the healthcare system and responsive when programmatic changes are necessary. The comments articulate a problem that the Cabinet considers a dangerous outcome of the certificate of need program when the system fosters unnatural monopolies limiting access to care and restricting patient choice that result from program protections rather than market forces. Further, the comments echo reports previously received from constituents complaining of lack of provider choice. Specific to emergency response and ambulance providers, issues of patient choice have been so significant that they precipitated a recent regulatory change to 202 KAR 7:555, Section 3(13) subsection an ambulance provider's disregard to patient choice to a disciplinary proceeding by the Kentucky Board for Emergency Medical Services. With respect to the proposed after-comment revision to 900 KAR 6:075, the Cabinet felt that the original language was very clear in regard to its plain intent. However, the concerns raised in this comment were validated by an administrative hearing officer's misinterpretation of the administrative regulation in a recent certificate of need administrative procedure involving Mikrod's CON application. Therefore, in recognition of the concerns raised in this comment, as validated by a recent administrative misinterpretation of the administrative regulation, the Cabinet has made amended after comments changes to the administrative regulation along lines similar to those requested in this comment.

(4) Subject Matter: COMMENTS IN OPPOSITION TO THE AMENDMENT TO 900 KAR 6:075: The following comments were all received in opposition to the amendment to 900 KAR 6:075:

(a) Comment: Ghayth Hammad, M.D., an independent primary care physician practicing in Morgantown, Kentucky, submitted a letter in opposition to the proposed amendment. Her comments state: "I am writing with regard to the provision of Emergency Medical Service in Warren County. I am an independent primary care physician with one of the busiest internal medicine practices in the region caring for patients here for over 18 years. During that time, I have been consistently impressed with the skill and capability of our ambulance service here in Warren County. Their leadership has been forward thinking, and I've watched as they pursued and achieved accreditations with the Commission on Accreditation of Ambulance Services and the Internal Academy of Emergency Dispatch. These accreditations are not awarded lightly-- and require services to consistently achieve quality metrics that are above the national norm. The service has relentlessly pursued better quality care for the residents of our county through their efforts

competition will bring more options and better outcomes for the people in our community..."

(b) Response: Thank you for your comments. The Cabinet recognizes that patient choice is a fundamental aspect of an optimal health system. Further, the TriStar Greenview Regional Hospital Board of Directors and community comments articulate opinions and beliefs about lack of patient choice in Warren County regularly reported from its region to the Cabinet. While the amendment to 900 KAR 6:075 does not guarantee that TriStar Greenview Regional Hospital will obtain a certificate of need to serve Warren County, it does remove one of the barriers precluding an additional provider from entering the market place and provides the opportunity for the applicant to be reviewed on its merits.

(2) Subject Matter: COMMENTS IN SUPPORT OF AMENDMENT TO 900 KAR 6:075 AND SOUTHERN KENTUCKY AMBULANCE SERVICE: The Cabinet received fifty-four (54) comments from physicians, surgeons, other medical providers and community members in support of both the amendment to 900 KAR 6:075 and the certificate of need application filed by Southern Kentucky Ambulance Service.

(a) Comment: Kamal P. Singh, MD, Board of Directors, Graves Gilbert Clinic, submitted comments stating: "On behalf of the nearly 190 physicians and nurse practitioners at Graves-Gilbert Clinic, and the 600,000+ patient visits we provided in 2017, we are writing to support the Class I EMS CON ambulance application by Southern Kentucky Ambulance Services in Warren County. For 80 years, we have been overwhelming provider of healthcare services to citizens of South Central Kentucky. We recognize the need for competition in order to provide cost effective ambulance services and allow patient choice at a time when they are the most weak and vulnerable..."

Medhat Grace, MD, Graves Gilbert Clinic, submitted comments stating: "As a doctor who has practices in the Bowling Green area for 21 years, I'm writing you in support of the Class I ambulance service Certificate of Need Application by Southern Kentucky Ambulance Service in Warren County. Warren County's economy and population are growing rapidly but our ambulance service offerings have not kept up. Currently, we have only one ambulance provider. More competition means more options for our residents and that is why I support this application. An additional ambulance provider will bring additional services to the community, increase patient choices and bring balance to the marketplace. I believe another provider and increased competition will lead to better quality and better service for the entire community..."

Zahid Fraser, MD, Graves Gilbert Clinic, submitted comments stating: "As a physician with 22 years of experience in the Bowling Green area, I am writing you to support the Class I ambulance service application by Southern Kentucky Ambulance Services in Warren County. Warren County is a growing market that needs an additional ambulance service. I see it every day. We have only one ambulance service in town, and it's owned and operated by one of the two hospitals. The hospital that runs the ambulance service often has long waits in the emergency room. Another ambulance service will bring much-needed balance and competition to the market. Again, I believe