CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Emergency Amended After Comments)

900 KAR 5:020E. State Health Plan for facilities and services.

RELATES TO: KRS 216B.010-216B.130

STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2.a

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)2.a requires the cabinet to promulgate an administrative regulation, updated annually, to establish the State Health Plan. The State Health Plan is a critical element of the certificate of need process for which the cabinet is given responsibility in KRS Chapter 216B. This administrative regulation establishes the State Health Plan for facilities and services.

Section 1. The [2020-2022] State Health Plan shall be used to:

(1) Review a certificate of need application pursuant to KRS 216B.040; and

(2) Determine whether a substantial change to a health service has occurred pursuant to KRS 216B.015(29)(a) and 216B.061(1)(d).


(2) This material may be inspected, copied, or obtained, subject to applicable
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East Main Street, 5E-A, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to
4:30 p.m. This material may also be viewed on the Office of Inspector General's website
at: https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx.
900 KAR 5:020E, Amended After Comments

REVIEWED:

4/6/2022

Date

[Signature]

Adam Mather, Inspector General
Office of Inspector General

APPROVED:

4/14/2022

Date

[Signature]

Eric C. Friedlander, Secretary
Cabinet for Health and Family Services
REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation: 900 KAR 5:020E, Amended After Comments
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; sbrammerbarnes@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(1) Provide a brief summary of:
(a) What this administrative regulation does: This administrative regulation incorporates by reference the 2022 Update to the State Health Plan.
(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.010, 216B.015(28), and 216B.040(2)(a)(2.a.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes, KRS 216B.010, 216B.015(28), and 216B.040(2)(a)(2,a.., by establishing the State Health Plan’s review criteria used for determinations regarding the issuance and denial of certificates of need.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing the review criteria for certificate of need determinations.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: In response to public comments on 900 KAR 5:020E, this emergency amended after comments regulation makes the following changes to the State Health Plan (SHP):
   • Updates the edition date of the SHP on page i of the Plan;
   • Updates the language of pages 2 and 3 of the SHP as it relates to using the most recent quality indicators as one of the review criteria for hospitals that wish to transfer existing acute care beds to a new facility under common ownership located in the same county, including state university teaching hospitals;
   • Adds clarifying language on page 15 of the SHP as it relates to an application to establish new Level III special care neonatal beds by conversion of Level II special care neonatal beds to Level III special care neonatal beds; and
   • Adds clarifying language to Review Criteria 3 on page 52 of the SHP as it relates to ground ambulance services.
(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to address updates to the State Health Plan as required by KRS 216B.015(28).
(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes because it incorporates by reference the State Health Plan.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the statutes by establishing the review criteria for certificate of need determinations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects entities that submit certificate of need applications and affected persons as defined by KRS 216B.015(3). A total of 70 certificate of need applications were submitted to the cabinet in calendar year 2021 and 60 certificate of need applications were submitted in calendar year 2020.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities that submit a certificate of need application are subject to the criteria set forth in the State Health Plan.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The certificate of need application filing fee for nonsubstantive review and formal review is established in a separate administrative regulation, 900 KAR 6:020.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities subject to certificate of need approval must demonstrate that their proposal is consistent with the State Health Plan pursuant to KRS 216B.040(2)(a)2.a.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the Office of Inspector General for implementation of this amendment.

(b) On a continuing basis: There are no additional costs to the Office of Inspector General for implementation of this amendment on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this amendment.
(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This amendment does not establish or increase any fees.

(9) TIERING: Is tiering applied? (Explain why or why not) Yes, tiering is used as there are different certificate of need review criteria for each licensure category addressed in the State Health Plan.
FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 900 KAR 5:020E, Amended After Comments
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; sbrammerbarnes@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and may impact any government owned or controlled health care facility.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010, 216B.015(28), and 216B.040(2)(a)2.a.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate additional revenue for state or local government.
   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate additional revenue for state or local government during subsequent years.
   (c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.
   (d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): See response above.
Expenditures (+/-): This administrative regulation is anticipated to have minimal fiscal impact to the cabinet.
Other Explanation:
SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

Cabinet for Health and Family Services
Office of Inspector General
Division of Certificate of Need

900 KAR 5:020E. State Health Plan for facilities and services.

The State Health Plan, April 2022, is incorporated by reference. The State Health Plan establishes the review criteria used for determinations regarding the issuance and denial of certificates of need. Changes to the January 2022 State Health Plan (SHP) include the following:

- Updates the edition date of the SHP on page i of the Plan;
- Updates the language of pages 2 and 3 of the SHP as it relates to using the most recent quality indicators as one of the review criteria for hospitals that wish to transfer existing acute care beds to a new facility under common ownership located in the same county, including state university teaching hospitals;
- Adds clarifying language on page 15 of the SHP as it relates to an application to establish new Level III special care neonatal beds by conversion of Level II special care neonatal beds to Level III special care neonatal beds; and
- Adds clarifying language to Review Criteria 3 on page 52 of the SHP as it relates to ground ambulance services.

The total number of pages incorporated by reference in this administrative regulation is fifty-nine (59).
STATEMENT OF CONSIDERATION
Relating to 900 KAR 5:020E

Cabinet for Health and Family Services, Office of Inspector General,
Division of Certificate of Need
(Emergency Amended After Comments)

I. The public hearing on 900 KAR 5:020E was held on March 21, 2022, at 9:00 a.m. in a Zoom meeting format by the CHFS Office of Legislative and Regulatory Affairs. In addition, written comments were received during the public comment period.

II. The following people submitted comments:

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<tr>
<th>Name and Title</th>
<th>Agency/Organization/Entity/Other</th>
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<tbody>
<tr>
<td>Sherri Craig</td>
<td>CHI Saint Joseph Health</td>
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<td>Market Vice President, Public Policy</td>
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<td>Heidi Schissler Lanham</td>
<td>Protection and Advocacy</td>
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<td>Legal Director</td>
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<td>Mark Leach</td>
<td>Emergent Care EMS</td>
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<td>Jody Prather, M.D.</td>
<td>Baptist Health</td>
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<td>Chief Strategy and Marketing Officer</td>
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<td>Russ Ranallo</td>
<td>Owensboro Health</td>
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<td>Vice President of Finance</td>
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<tr>
<td>Wade R. Stone</td>
<td>Med Center Health</td>
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<td>Executive Vice President</td>
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<td>David Turner</td>
<td>Heart and Soul Hospice</td>
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<td>Kara Daniel</td>
<td>Cabinet for Health &amp; Family Services</td>
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<td>Deputy Inspector General</td>
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<td>Adam Mather, Inspector General</td>
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<td>Kara L. Daniel, Deputy Inspector General</td>
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<td>Stephanie Brammer-Barnes, Contractor</td>
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III. The following people from the promulgating administrative body responded to the written comments:

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<th>Name and Title</th>
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<tbody>
<tr>
<td>Adam Mather, Inspector General</td>
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<tr>
<td>Kara L. Daniel, Deputy Inspector General</td>
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<tr>
<td>Stephanie Brammer-Barnes, Contractor</td>
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IV. Summary of Comments and Responses

(1) Subject Matter: Special Care Neonatal Beds

(a) Comment: Wade R. Stone, Med Center Health, provided the following comments: “Med Center Health would like to comment specifically on the new criterion no. 4 concerning an application to establish new Level III special care neonatal beds, which reads as follows:

Notwithstanding criterion 1, an application for additional Level III special care neonatal beds by conversion of Level II special care neonatal beds to Level III special care neonatal beds shall be consistent with this Plan.

We believe that the intent of this new criterion no. 4 was to state that an application to establish a new Level III special care neonatal service through conversion of Level II special care neonatal beds shall be consistent with the SHP. However, we believe that the wording of criterion no. 4 may lead some to believe that it may be used only in circumstances in which an applicant already operates a Level III special care neonatal service. Such an interpretation would render criterion no. 4 superfluous because KRS 216B.020(1) already permits “the redistribution of beds by licensure classification within an acute care hospital so long as the redistribution does not increase the total licensed bed capacity of the hospital.

To avoid any confusion, we suggest that the language of criterion no. 4 be amended as follows:

Notwithstanding criterion 1, an application to establish new Level III special care neonatal beds by conversion of Level II special care neonatal beds to Level III special care neonatal beds shall be consistent with this Plan.

We believe that this amendment to the language will clarify the intent. Furthermore, we believe that this language is consistent with the purposes of Kentucky’s CON program because it will allow an existing operator of Level II special care neonatal beds to submit an application to fulfill a need for Level III special care neonatal service without increasing the total licensed bed capacity of the hospital.”

Jody Prather, M.D, Baptist Health, provided similar comments regarding special care neonatal beds and recommended the same change to criterion no. 4.

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General agrees with the commenters’ understanding of the cabinet’s intended change and will add the recommended clarification to the State Health Plan.

(a) Comment: Russ Ranallo, Owensboro Health, provided the following comments: “The new neonatal State Health Plan language includes the following:
'Notwithstanding criterion 1, an application for additional Level III special care neonatal beds by conversion of Level II special care neonatal beds to Level III special care neonatal beds shall be consistent with this Plan.'

As we read this language we believe the intent of this change is to allow current Level III NICU programs to add to their Level III bed compliment via conversion of Level II beds to Level III.

We would not support and would ask for removal of the language if it means a hospital with only neonatal Level II beds is allowed to convert beds to new Level III beds and establish a Level III program that hasn’t been in existence before. If this is the intent we would also note there is no basis for determining that there is a need for an emergency regulation to allow the establishment of Level III neonatal beds in this matter.

The Kentucky Hospital Association reviewed neonatal CON requirements in other states and did not find any CON programs that allowed establishment of Level III neonatal beds simply because the applicant was providing Level II neonatal service.

If the Cabinet believes there is a need for additional Level III neonatal beds we would ask a review/study be conducted to determine if the planning area needs adjustment. The Level III bed is the statewide area while the Level II bed is the area development district."

(b) Response: The Cabinet for Health and Family Services, Office of Inspector General appreciates the comments on the State Health Plan. However, as stated above, the cabinet is making a change to clarify that an application to establish new Level III special care neonatal beds by conversion of Level II special care neonatal beds shall be consistent with this Plan. This is intended to address increased need for Level III special care neonatal services in areas of the state without Level III beds, making these services available closer to home and family for babies needing this care.

(2) Subject Matter: Nonsubstantive Review for Ambulance Services Under Certain Conditions

(a) Comment: Mark Leach, Emergent Care EMS, stated the following during the public hearing: "I am commenting on the regulation change to create a new type of classification for a Class I and lower the review standard for the health facility-based ALS or BLS ambulance service to nonsub review.

It appears that this is a solution looking for a problem, and I say that because I am not aware of what evidence the cabinet is relying on to support this rule change. When you review the certificate of need search tool for applications for ground ambulance, there are very few that have actually been submitted by hospitals in the
most recent years. So, it has not been demonstrated that the current system needs to be changed in order to address what they feel is a need for a new type of ambulance service. And I shouldn’t just limit that to hospitals, but health facilities.

So, I say again, I’m not sure what evidence the Cabinet is relying on, and lacking any evidence, particularly substantial evidence, this would be a capricious rule change. Moreover, it would jeopardize the provision of emergency services statewide. This was an issue that was addressed several years ago when the State Health Plan sought to be amended to remove ambulance services from formal review, making it such that all ground ambulance applications would be nonsubstantive review.

And at the same time, there was a great number of comments from county providers that noted that if you take away the more reliably paid nonemergency runs from the services' inventory such that they are doing a higher percentage of the less likely to be paid emergency runs, they would not be fiscally feasible. They would be operating in the red all the time because they balance out the less likely paid emergency runs by doing the more likely paid nonemergency transports.

What this regulation change would do would be to provide to health facilities that are already at least financially feasible because they are operating and, then, giving them another review line that is needed for the area emergency ambulance providers. Moreover, because the rule change allows for ALS services, that means that you are taking paramedics which are a very rare resource in our state right now – any ambulance service would attest to this – and you’re offering them the opportunity to take the less risky, more likely to be paid, less stressful nonemergency runs instead of being able to respond to the emergency runs in the counties in which they are situated.

I would ask the cabinet to go back and look at those comments from when they sought to remove the ambulance service from the State Health Plan because the same points there are effectively made here. Overall, this will weaken ambulance response, not strengthen it, and I would ask that the Cabinet not move forward with this change. Thank you.”

In addition to his verbal testimony at the public hearing, Mr. Leach provided the following written comments: “I write on behalf of Emergent Care EMS LLC (Emergent®) in opposition to 900 KAR 5:02E and 900 KAR 6:075E (collectively referred to herein as the ‘emergency regulations’), specifically the removal of health facility-based ground ambulance providers limited to non-emergency scheduled transports from formal review. This proposed change runs exactly counter to the purposes of Kentucky’s certificate of need (CON) law. Emergent made verbal comments at the March 21, 2022 hearing on the emergency regulations; these comments are made in addition to those made at the hearing.

Ambulance economics
Most people think of ambulances responding to 9-1-1 calls, with sirens screaming as they run down the road to save a life. Emergency runs are the most costly runs to an ambulance service for several reasons:

1. They require 24 hour operations with higher level personnel, a paramedic and an EMT;
2. They involve using more supplies and equipment; and, critically,
3. They are the most likely not to be reimbursed.

How full-service ambulance companies cover those costs is through providing non-emergency transports. These runs are more cost-effective for the opposite reasons:
1. They can be responded to by a first responder and an EMT;
2. They typically use few supplies and equipment; and,
3. They are the most likely to be reimbursed.

Non-emergency runs are what allow ambulance companies to be there when citizens most need them: in an emergency. The emergency regulations put this balance in jeopardy.

Ramifications if proposed changes are accepted

If permitted to take effect, the emergency regulations would put CON applications for health facility based ground ambulance services limited to non-emergency scheduled transports through the much more deferential non-substantive review process. Instead of being evaluated on whether the applicant operates in a cost-effective manner, offering a more cost-efficient alternative to existing services, and provides quality service, the application will be reviewed solely on whether there is a need for the new service, and need is presumed. See KRS 216B.095(4), 900 KAR 6:075(7).

Beyond risking bringing in providers that fail to provide quality services, this new system will result in services only doing the most cost-effective runs, the non-emergency runs. This will result in a domino effect endangering citizens’ health and resulting in higher taxes.

As new providers siphon off the non-emergency runs, the percentage that non-paying emergency runs make up of existing full service providers’ transports will increase. No company can continue operating at loss, which will put the local governing body and its citizens in a tough position for the publicly operated services: either the emergency responders will close operations or they will have to be subsidized through a local tax. Given this option—and no way to compel the new companies to provide emergency services—responsible public officials will have no choice but to impose a new tax, or raise an existing tax levy, for ambulance services. For private providers, charges will have to increase to cover the shortfall from not having reliably paid nonemergency transports. As a result, the emergency
regulations will make emergency ambulance services more expensive, either through higher taxes or higher charges for service.

This effect runs entirely counter to the entire purpose of the certificate of need law, namely to provide safe, adequate, and efficient health care services. The proposed change to the SHP will result in the exact opposite: citizens will be endangered due to inadequate service and will result in greater public spending to ensure emergency response.

Existing system for ambulance service should remain unchanged.

The emergency regulations are a baseless solution looking for a problem.

Under the existing regulations and State Health Plan ("SHP"), applicants who wish to just cherry-pick the nonemergency runs must prove that the existing providers are not serving those runs. Similarly, where two applicants are considered, the one offering the higher level of service, i.e. performing both emergency and non-emergency runs, is favored by the SHP. The SHP further requires applicants to notify all licensed ambulance services operating in the proposed service area of the applicant's intent to apply to provide service. This would no longer be required if ground ambulance is removed from the SHP, and, given the very short turnaround time required by statute for non-substantive review, existing providers would not have the notice or time to prepare if they wished to oppose an unnecessary, or worse, poor-quality provider from moving into their county and sweeping up the non-emergency runs.

The SHP currently addresses these concerns and should remain unchanged. As mentioned in the verbal comments at the March 21 hearing, there is no established basis for the proposed change. Emergent was the only party to offer comments, despite close to twenty other attendees, several of whom represent hospitals seeking the change to the SHP. So, the only evidence in the record regarding this regulatory change is Emergent's opposition.

Further, the Cabinet has institutional knowledge based on its responsibility of operating the Office of CON, which collects all CON applications. It would be one thing if there were a number of applications by health facilities seeking to establish an ambulance service that had been improperly denied or that had been granted because there was such clear need demonstrated in the hearings. But, the fact is, there is not. There are no applications in recent years where an applicant proved at a hearing that the existing ambulance providers cannot meet the need for scheduled non-emergency transports. Similarly, there are no applications by health facilities that were denied but shown in an appeal to Franklin Circuit Court to have been improperly denied. As such, there is zero evidence, much less the required substantial evidence, to support this regulatory change. Without substantial evidence, allowing the emergency regulations to take effect would be the definition of arbitrary and capricious action.
Aggravating an existing crisis of personnel shortage

The emergency regulations will further threaten the provision of quality emergency and non-emergency ambulance service by aggravating an existing crisis: the shortage of qualified, trained emergency medical technicians (EMTs) and paramedics.

Ask any ambulance service in the state and they will tell you one of the biggest challenges they have is staffing their service with qualified, trained EMTs and paramedics. There is a scarcity of personnel in this career field. In order to staff a BLS service, it requires at least an EMT and to staff an ALS service it requires at least a paramedic, each trained staff member riding in the back of the ambulance rendering care to the patient. EMTs and paramedics are leaving the field of ambulance services to seek better pay, more reliable hours, and less traumatic scenes by being hired on by health facilities, particularly hospitals. As a result, existing services struggle to fully staff their services. The emergency regulations will greatly exacerbate this problem.

With the proposed change carving out Class I ALS/BLS services that are health facility based to do only non-emergency transports, it creates the attractive service that will siphon off personnel from full service ambulance providers. These health facility based services will offer exactly what is causing EMTs and paramedics to leave full service providers: better pay, more reliable hours (since transports rarely occur during nighttime), and fewer trauma scenes. The proposed change will wreck staffing for full service ambulance providers endangering every citizen that needs timely emergency response.

Conclusion

There has not been given a reason to justify the emergency regulations. Rather, in the public comments made at the March 21, 2022 hearing and in the filing of written comments, including this one, abundant reasons have been given as to why the emergency regulations would be counter to the purposes of the CON program.

Duplicative services would enter existing providers’ service areas, syphoning off the nonemergency transports and trained personnel, leaving emergency services understaffed and needing public subsidization through taxes or higher charges for private providers. Quality would suffer as emergency services become less cost feasible endangering all citizens in need of emergency response.

The current system permits private providers, like Emergent, to be good community partners as well as sound businesses, by providing the proper mix of emergency and non-emergency runs to make a full service emergency responder cost feasible and fully staffed. The emergency regulations will endanger our citizens, increase taxes, increase ambulance charges, and lower quality services. There has not been
demonstrated by substantial evidence a need for the emergency regulations. The emergency regulations should not go into effect."

(b) Response: The Cabinet for Health and Family Services amended the State Health Plan to address widespread complaints from hospitals, long-term care facilities, hospice agencies, and others about ongoing delays with nonemergency ambulance transportation.

It should also be noted that the passage of HB 777, anticipated to take effect in July 2022, will grant a certificate of need exemption until July 1, 2026, to all hospital-owned ambulances that provide nonemergency and emergency transport services originating from the hospital, and city or county-owned emergency ambulances that provide transport services within their jurisdictional boundaries and comply with the other requirements of Section 9(8) of the Act. In addition, HB 777 will grant nonsubstantive review until July 1, 2026 to hospital-owned ambulances and city or county-owned ambulances seeking to provide services that do not qualify for the certificate of need exemption of Section 9(7) or (8) of the Act.

After the public comment period for the ordinary version of 900 KAR 5:020 and 900 KAR 6:075 ends on April 30, 2022, the cabinet will amend the language of 900 KAR 6:075, Section 2(3) in the separate "ordinary" version of the Statement of Consideration (SOC) and Amended After Comments (AAC) regulation to align with the passage of HB 777. The ordinary SOC and AAC regulation will be filed with the Legislative Research Commission no later than June 15, 2022.

The cabinet made one new change to the language on page 52 of the State Health Plan to align with the Emergency Amended After Comments version of 900 KAR 6:075E, Section 2(3)(e).

(3) Subject Matter: Cardiac Catheterization Service

(a) Comment: Sherri Craig, CHI Saint Joseph Health, provided the following comments: "We appreciate the Cabinet for Health and Family Services’ clarification that the addition of a cardiac catheterization program at a hospital shall be based on the existing program’s utilization, rather than a specific laboratory’s utilization.

To further ensure access to cardiac catheterization services across the Commonwealth, especially in rural areas where distance and travel to a comprehensive center can be burdensome for patients and their families, we recommend amending the criteria for approval of these services if the applicant, a licensed Kentucky acute care hospital, is affiliated with a collaborating tertiary hospital with an active comprehensive cardiac surgical program, including open heart surgery. Exceptional cardiac surgery programs are housed in non-teaching hospitals throughout Kentucky and are in a strong position to provide clinical support and quality oversight to affiliated hospitals offering diagnostic and therapeutic services. These non-teaching tertiary hospitals have collaborative
agreements to provide supportive services through affiliation agreements."

(b) Response: The Cabinet for Health and Family Services appreciates the comments regarding the State Health Plan. However, due to the potential for increased patient complications, the cabinet will not be amending the State Health Plan to allow acute care hospitals without open-heart surgery capability to provide comprehensive cardiac catheterization services under an affiliation agreement with the cardiology program of a tertiary hospital that has an active comprehensive cardiac surgical program.

(a) Comment: Russ Ranallo, Owensboro Health, provided the following comments: "The new State Health Plan language includes the following:

'According to the most recent edition of the Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization, each existing fixed-site diagnostic laboratory in the planning area shall have performed at least 250 adult diagnostic procedures in the last twelve (12) month reporting period. Each existing fixed-site comprehensive program (laboratory) (diagnostic and therapeutic) shall have performed at least 550 adult procedures in the last twelve (12) month reporting period.'

'Program' in the language is not defined. Is it each hospital with catheterization services in the planning area or could multiple hospitals under common ownership in the planning area be considered a 'program'?

What study, research, or information led to the changing 'laboratory' to 'program' but not changing the number of procedures required in the section?

We ask for clarification on these items before we provide comments."

(b) Response: The change to the State Health Plan would require every fixed-site comprehensive cardiac catheterization services program in the planning area, rather than each existing laboratory in the planning area, to have performed at least 550 adult procedures in the last 12 months before an application could be consistent with the State Health Plan.

(4) Subject Matter: Intermediate Care Facilities for Individuals with and Intellectual Disability (ICF/IID)

(a) Comment: Heidi Schissler Lanham, Protection and Advocacy, provided the following comments: "Kentucky Protection and Advocacy is an independent state agency that provides legally-based advocacy for individuals with disabilities throughout the Commonwealth, including individuals with intellectual and developmental disabilities. Here are our comments regarding the above-referenced regulation and the 2022 Update to the State Health Plan."
Intermediate Care Facilities for Individuals with an Intellectual Disability (ICF/IID) (page 38): The Cabinet should change the review criteria to prohibit the transfer of public ICF/IID beds to private facilities. Transferring public ICF/IID beds to private ICF/IID facilities violates the spirit of the Cabinet’s agreement in Michelle P. v. Birdwhistell, et al, U.S. District Court, Eastern District of Kentucky, Frankfort Division, Civil Action #02-23- JMH, in which the Cabinet agreed not to back-fill publicly funded ICF/IID beds. Such a prohibition also comports with Title II of the Americans with Disabilities Act, as interpreted by the U.S. Supreme Court in Olmstead v. L.C., 1 which requires states to provide services to individuals with disabilities in the most integrated setting appropriate to their needs—usually the community. This is another one of the reasons why Kentucky continues to decrease the number of individuals in public ICF/IID beds.

The new review criteria should read: ‘An application for a new ICF/IID shall not be consistent with this Plan unless it is limited to a transfer of ICF/IID beds from an existing private ICF/IID facility to the proposed private ICF/IID facility. An application to increase the number of beds at an existing private ICF/IID facility shall not be consistent with this Plan unless the increase in beds is accomplished by transferring beds from an existing private ICF/IID facility.’”

(b) Response: The Cabinet for Health and Family Services appreciates the comments regarding the State Health Plan. However, the cabinet will retain the language of the State Health Plan as written to avoid eliminating the cabinet’s ability to transfer beds from large, public ICF/IID facilities to small, freestanding ICF/IID facilities in the community.

(5) Subject Matter: Hospice

(a) Comment: David Turner, Heart and Soul Hospice, provided the following comments: On behalf of Heart and Soul Hospice, please accept these written comments on the proposed changes to 902 KAR 5:020E and the 2022 Update to the Kentucky State Health Plan that is incorporated therein by reference. These comments relate specifically to the hospice review criteria in the Kentucky State Health Plan.

On April 30, 2021, Heart and Soul Hospice submitted a comment letter to the Cabinet for Health and Family Services, Office of Inspector General proposing changes to the hospice criteria in the Kentucky State Health Plan. The proposed amendment would allow for hospice agencies that are 100% owned and operated by minorities to satisfy the hospice State Health Plan criteria. The proposed amendment would only allow an exception to the existing State Health Plan review criteria and applicants would still be required to meet all of the other formal review criteria for certificate of need applications. Specifically, applicants would still be required to establish need, accessibility, interrelationships and linkages, quality of care, and cost effectiveness of the proposal.

The updated 2022 Kentucky State Health Plan was filed on January 27, 2022
through an emergency administrative regulation, 900 KAR 5:020E, and, disappointingly, it did not include changes to the hospice review criteria. Despite the fact that there were no comments filed in opposition to the proposed changes and acknowledgments from Cabinet representatives, community leaders, health care workers, and residents in Kentucky about the need for revised criteria, the hospice review criteria remain unchanged, allowing no opportunity for a new hospice provider to be approved to provide services in 114 out of Kentucky’s 120 counties.

As background, Heart and Soul Hospice is a hospice agency that is 100% owned and operated by minorities. Heart and Soul serves everyone but its primary goal is to increase education, opportunity, and access to hospice services for African American and other minority communities who have historically used hospice services at significantly lower rates. Heart and Soul’s owners have ties to Kentucky and know firsthand that there is a need for increased access to hospice services for minorities in many of its communities. In order to provide hospice services in Kentucky, Heart and Soul must obtain a certificate of need (CON) from the Cabinet. A CON application to establish a hospice agency in Jefferson County cannot be approved under the current State Health Plan in a majority of Kentucky’s counties. In fact, there has not been a CON application approved for a new hospice agency in Kentucky since 2003.

Again, the proposed change is an effort to increase access to hospice services for Kentucky’s minority populations. As described in more detail in the attached letter, the following facts support the proposed change:

- Kentucky is one of only approximately eleven states that regulates the development of hospice programs through CON.
- The proposed change will increase access to hospice services for Kentucky’s minority populations. Under the current Hospice Services review criteria, no CON application to expand or establish hospice services can be approved in 114 of Kentucky’s 120 counties.
- There are only 23 licensed hospice agencies serving Kentucky’s 120 counties. A majority of Kentucky counties (approximately 78) have only one hospice provider, resulting in no patient choice. Kentucky’s most populated county, Jefferson County, has only one hospice provider, which is Hosparus, Inc. Hosparus is currently licensed to serve 27 Kentucky counties. We don’t dispute that Hosparus provides good care; however, it is the only licensed hospice provider in Jefferson County and in each of the contiguous counties: Bullitt, Oldham, Shelby, and Spencer Counties. Kentucky’s second most populated county, Fayette County, also only has one hospice provider, Hospice of the Bluegrass, Inc.
- It is highly unusual for populations these sizes to be served by one hospice provider. It allows for no patient choice or fair competition.
- None of Kentucky’s existing licensed hospice agencies are wholly minority owned and few have minority representation on their Boards.
- The current hospice review criteria went into effect in 2007 and there has not been a single CON application approved for a new hospice agency in Kentucky.
since 2003.

- Kentucky has a growing elderly population. This aging typically results in more deaths and a greater demand for hospice services. The target population for hospice providers is individuals who are ages 65 and older and this population is growing at a much faster rate than the overall population in Kentucky.
- More specifically, the 65 and older African American population in Kentucky is growing at a surprisingly fast rate, faster than the 65 and older white population.
- According to data from the National Hospice and Palliative Care Organization, Hospice utilization is lower overall in Kentucky than it is in a vast majority of other states (Kentucky ranks 44th).
- It is indisputable that African Americans and other minorities access hospice services at an even lower rate. African Americans use hospice services at far lower rates than white people do and are more likely to experience untreated pain at the end of their lives.
- Studies suggest and our experience in other markets shows that a hospice agency owned and operated by minorities will be able to reach a larger percentage of minorities who are appropriate for hospice care due to understanding of the cultural, political, and economic factors that go into healthcare decisions in these communities.
- I have had multiple conversations with community leaders and health care professionals in Kentucky who agree that additional resources are necessary to promote access and care for minority populations who are transitioning to end of life.”

(b) Response: The Cabinet for Health and Family Services appreciates the comments regarding the State Health Plan. However, at this time, the cabinet will retain the certificate of need requirements for hospice applicants as written.

(6) Subject: Acute Care Beds

(a) Comment: Kara Daniel, Deputy Inspector General, Cabinet for Health & Family Services, provided the following comments: The Overall Hospital Quality Star Ratings summarize hospital quality data on the Hospital Compare website. CMS updates the overall star ratings on a bi-annual schedule during the Hospital Compare releases but the months in which they are released may vary. Therefore, the cabinet will replace the phrase “for three (3) out of the last four (4) reported quarters” on page 3 of the State Health Plan with “on the two (2) most recent updates to the overall star ratings”.

Additionally, in lieu of meeting the overall star ratings if the hospital is a state university teaching hospital, the cabinet will clarify that such hospitals must exceed the minimum number of quality measures required to receive supplemental university directed payments from Kentucky Medicaid for the state fiscal year preceding the date the application was filed.

(b) Response: The cabinet will amend page 3 of the State Health Plan as stated above.
Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

The public hearing on this emergency administrative regulation was held on March 21, 2022. In addition to testimony provided during the hearing, written comments were received during the public comment period. The Cabinet for Health and Family Services, Office of Inspector General responded to the comments and amends the emergency administrative regulation as follows:

Page 1
Section 2(1)
Line 19
After “Plan”, ”, insert “April 2022”.
Delete “January 2022”.

Material Incorporated by Reference

State Health Plan Cover Page
Edition Date in Top Right Corner
After “Date:”, insert “April”
Delete “January”.
Edition Date in Middle of Page
After “Plan”, insert “April”
Delete “January”.

Page 3
I. Acute Care
A. Acute Care Hospital
Review Criteria 2.d
After “d.”, insert the following:

No more than fifty (50) percent of the existing hospital’s acute care beds shall be transferred to the new facility; and

e. i. If the existing hospital is a state university teaching hospital, the existing hospital exceeded, by at least one (1), the minimum number of quality measures required to receive supplemental university directed payments from Kentucky Medicaid for the state fiscal year preceding the date the application was filed; or

ii. If the existing hospital is not a state university teaching hospital, After “(3) stars or higher”, insert the following:

on the two (2) most recent updates to the overall star ratings
Delete the following:
for three (3) out of the last four (4) reported quarters
After “filed”, deleted the following:
; and
e. No more than fifty (50) percent of the existing hospital’s acute care beds shall be transferred to the new facility

Page 15
I.D. Special Care Neonatal Beds
Review Criteria 4.
After “application”, insert “to establish new”.
Delete “for additional”.

Page 52
V. Miscellaneous Services
A. Ambulance Service
Review Criteria 3.
After “provide”, delete “nonemergency”.
After “Section”, insert “2(3)(e)”.
Delete “2(3)(d)”.