CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amended After Comments)

900 KAR 5:020. 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 [~~2018 Update to the 2017-2019~~] 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).

Section 2. Incorporation by Reference. (1) The "2020-2022 [~~2018 Update to the 2017-2019~~] State Health Plan", **August [~~April~~]** 2020 [~~November 2018~~], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, Division of Certificate of Need, 275 East Main Street, 5E-A, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 5:020

8/12/2020

Adam D. Mather
Inspector General
Office of Inspector General

Date

APPROVED:

8/13/2020

Eric C. Friedlander
Secretary, Cabinet for Health and Family Services

Date

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation:	900 KAR 5:020
Agency Contact:	Kara Daniel
Phone Number:	(502) 564-2888
Email:	KaraL.Daniel@ky.gov
Contact Person:	Donna Little
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 2020-2022 State Health Plan.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes.

(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 suggestions and comments submitted to the Cabinet by interested groups, the amendment to this administrative regulation filed April 3, 2020, made the following changes to the State Health Plan (SHP):

- Updates the title and edition date of the SHP on page i of the Plan;
- Updates the title of the SHP on page iii of the Plan under the heading "Purpose";
- Adds language to page iii to establish a temporary waiver of certain certificate of need requirements as authorized by an Executive Order during a State of Emergency declared as the result of a public health crisis;
- Adds language to the review criteria on page 37 to clarify the prohibition against transferring public intermediate care facility for individuals with an intellectual disability (ICF/IID) beds to a private ICF/IID;
- Revises the language of the review criteria on page 39 to clarify 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; and
- Revises the language of the review criteria on pages 52 – 54 to enable a Kentucky-licensed acute care hospital to establish an ambulatory surgical center

in the same county as the hospital

Based upon comments received during the public comment period and because of the uncertainty created by the ongoing COVID-19 pandemic, the Cabinet has made the following substantive revisions in the proposed "Amended After Comments" administrative regulation:

- The proposed substantive changes to the review criteria on page 37 regarding a prohibition on transferring public intermediate care facility for individuals with an intellectual disability (ICF/IID) beds to a private ICF/IID were removed;
- The proposed substantive changes to the review criteria on page 39 regarding cardiac catheterization programs were removed; and
- The proposed substantive changes to the review criteria on pages 52-54 regarding ambulatory surgical centers were removed.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to address annual updates to the State Health Plan as required by KRS 216.015(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 2020-2022 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 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 certificate of need applicants and affected persons as defined by KRS 216B.015(3). In calendar year 2018, eighty-three (83) certificate of need applications were filed and in calendar year 2019, eighty-four (84) applications were filed.

(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 2020-2022 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): There will be no additional costs to entities to comply with this amendment.

(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: No additional costs will be incurred to implement this administrative regulation.

(b) On a continuing basis: No additional costs will be incurred to implement this administrative regulation 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 administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation 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 5:020
Agency Contact: Kara Daniel
Phone Number: (502) 564-2888
Email: KaraL.Daniel@ky.gov

Contact Person: Donna Little
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 administrative regulation will not generate 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 administrative regulation will not generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

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 5:020. State Health Plan for facilities and services.

The 2020-2022 State Health Plan, August 2020, 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 State Health Plan (SHP) include the following:

- Updates the title and edition date of the SHP on page i of the Plan;
- Updates the title of the SHP on page iii of the Plan under the heading “Purpose”;
- Adds language to page iii to establish a temporary waiver of certain certificate of need requirements as authorized by an Executive Order during a State of Emergency declared as the result of a public health crisis;
- Restores the original review criteria on page 37 regarding the transfer of public intermediate care facility for individuals with an intellectual disability (ICF/IID) beds to a private ICF/IID;
- Restores the original review criteria on page 39 regarding the addition of a cardiac catheterization program at a hospital; and
- Restores the original review criteria on pages 52 – 54 regarding the opening of ambulatory surgical centers.

The total number of pages incorporated by reference in this administrative regulation is fifty-five (55).

STATEMENT OF CONSIDERATION
Relating to 900 KAR 5:020

Cabinet for Health and Family Services
Office of Inspector General
Division of Health Care

Amended After Comments

I. The public hearing on 900 KAR 5:020 was held on June 22, 2020, at 9:00 a.m. electronically via Zoom.

II. The following people attended the virtual public hearing, provided verbal testimony at the hearing regarding 900 KAR 5:020, or provided written comments:

NAME AND TITLE	AGENCY/ORGANIZATION/ENTITY/OTHER
Stephen Abresch, Associate Director of Government Affairs, State Affairs	Ambulatory Surgery Center Association
Jay Chappell, Vice President of Operations	American Medical Response
Hollie H. Phillips, Vice President, Corporate Strategy	Appalachian Regional Healthcare, Inc.
Isaac Hallam, Director of Corporate Strategy	Appalachian Regional Healthcare, Inc.
Jody Prather, M.D., Chief Strategy and Marketing Officer	Baptist Health
Timothy Marcum, Assistant Vice President of Planning	Baptist Health
Michael J. Yungmann, Market President, Kentucky	Bon Secours Mercy Health
Chris Stevenson, President/CEO	Cedar Lake
Sherri Craig, MBA, Market Vice President, Public Policy	CHI Saint Joseph Health
Kathy Love, Chief Strategy Officer	CHI Saint Joseph Health
Jeff R. Ellison, Chief Operating Officer	Commonwealth Pain and Spine
Karen Hartman, President and CEO	Corazon, Inc.
Lorraine Buck, Vice President, Consulting	Corazon, Inc.
Kristin Truesdell, Vice President Business Consulting and Informatics	Corazon, Inc.

Marie Alagia Cull, Attorney	Cull & Hayden, PSC
Holly Turner Curry, Attorney	Cull & Hayden, PSC
David Dirr, Attorney	Dressman, Benzinger, and LaVelle, PSC
Ben Fiechter	Fiechter Law, PLLC
Tyler Glick	Glick Strategies
David S. Samford, Attorney	Goss Samford, PLLC
Colleen McKinley, Attorney	Jennie Stuart Medical Center
Troy Walker, President	Kentucky Ambulance Providers Association
Elizabeth A. “Betsy” Johnson, President/Executive Director	Kentucky Association of Health Care Facilities and Kentucky Center for Assisted Living
Bruce Linder, Executive Vice President	Kentucky Association of Health Care Facilities and Kentucky Center for Assisted Living
Evan Reinhardt, Executive Director	Kentucky Home Care Association
Nancy C. Galvagni, President and CEO	Kentucky Hospital Association
Heidi Schissler Lanham, Legal Director	Kentucky Protection and Advocacy
Timothy Veno, President/CEO	LeadingAge Kentucky
Dr. Andrew Henderson, CEO	Lexington Clinic
Eric Riley	Lexington Clinic
Libby Milligan, Principal	McCarthy Strategic Solutions, LLC
Wade R. Stone, Executive Vice President	Med Center Health
David Gray, Senior Vice President	Med Center Health
Michael J. Yungmann, President	Mercy Health-Lourdes
Brandy Cantor	MML&K Government Solutions, on behalf of Kentucky Association of Hospice
Mary Jo Bean, Senior Vice President, Planning & Business Analysis	Norton Healthcare
Dr. Anand Gupta	Paramount Surgery Center, LLC
Joseph Pritchard, President and CEO	Pinnacle Treatment Center
Anjello Luciano, Administrative Associate	Platt HMC, Inc.
Michael R. Adkins, President	Portsmouth Emergency Ambulance Service, Inc. (“PEASI”), and Greenup Emergency Ambulance Service LLC (“GEAS”)
Daniel Winkler, Vice President - Operations	Southern Kentucky Surgicenter, LLC
Garren Colvin, President and Chief Executive Officer	St. Elizabeth Healthcare
Representative John Blanton	State Representative, 92nd District
Senator Phillip Wheeler	State Senator, 31st District
Janet A. Craig, Attorney	Stites & Harbison, PLLC; Pikeville Medical Center; and Endoscopy and Surgical Center

	of Lexington Clinic and the Lexington Clinic Surgery Center
Randall S. Strause	Strause Law Group, PLLC
Daniel Riggs, Group President	Surgical Care Affiliates
Lindsay Haynes Lowder, Vice President, Payment Innovation Solutions	Surgical Care Affiliates
Mike Sherrod, Chief Executive Office	TriStar Greenview Regional Hospital
Mark Newman, Executive Vice President for Health Affairs	UK HealthCare
William A. Jones, Regional Senior Vice President and CEO	WellCare of Kentucky

III. The following people from the promulgating administrative body responded to the public comments:

NAME AND TITLE

Adam Mather, Inspector General, Office of Inspector General
Kara Daniel, Deputy Inspector General, Office of Inspector General

IV. SUMMARY OF COMMENTS AND RESPONSES

(1) Subject: Transfer of ICF/IID beds

(a) Comment: Chris Stevenson, President/CEO, Cedar Lake, provided the following comments:

“My name is Chris Stevenson and I am the President/CEO of Cedar Lake. It has been suggested that the state add language to prohibit the transfer of beds in public intermediate care facilities to private intermediate care facilities In the Regulatory Impact Analysis and Tiering Statement. Cedar Lake would like to stress how important it is to maintain the flexibility of allowing the transfer of beds from public ICFs to private ICFs. In 2006, the cabinet asked Cedar Lake to allow for the transfer of 11 beds from Oakwood to Cedar Lake because of their desire to reduce capacity at Oakwood and to respond to requests from parents and guardians of those 11 individuals who desired to transfer their loved one to a private ICF. Maintaining this option is important and allows for flexibility between public and private ICFs to respond to changes in our shared dynamic support service structure.

Over the last several years, Kentucky has made a strong effort to shrink the size of its public institutions to keep pace with the Department of Justice’s (DOJ) national movement to reduce or close large facilities in favor of smaller, more integrated settings. Because of the DOJ’s effort, Kentucky has significantly reduced the usage of its Intermediate Care

beds in Kentucky…..And while these beds are more expensive than community waiver beds in the Supports for Community Living Waiver program, the Intermediate Care bed offers more robust support, complete with 24-hour intensive nursing and therapy care. Unfortunately, the waiver program does not even come close to providing the financial resources needed to fund adequate care for people with intense daily nursing and therapy needs.

With limited options and the state's ongoing initiative to reduce the usage of 'intermediate care' beds, families have had little choice but to place their loved ones in psychiatric facilities, nursing homes, and, at times, back home with their families. All of these choices have devastating consequences because of the lack of appropriate staffing and expertise to deal with chronic medical issues and intense daily nursing supports required to maintain a true quality of life for these individuals. Over the last several years, a disturbing trend has been discovered. Individuals inappropriately placed have severe negative outcomes, including death, due to the lack of available resources in the community – and Cedar Lake's waiting list for these critically needed services has grown to 8+ years, leaving aging parents to care for their significantly disabled sons and daughters at home. Needless to say, these families are left feeling confused and hopeless about the future of their loved one.

Again, maintaining the option to transfer ICF beds from one facility to another is important and allows for flexibility between public and private ICFs to respond to changes in our shared dynamic support service structure. I respectfully request that you maintain the current language allowing for the transfer of beds in public intermediate care facilities to private intermediate care facilities in the Regulatory Impact Analysis and Tiering Statement."

(b) Response: The Cabinet appreciates the comments from Chris Stevenson, President/CEO, Cedar Lake, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

The Cabinet drafted the proposed amendment before Kentucky began to experience the effects of the global COVID-19 pandemic and without an understanding of the unexpected and comprehensive ways in which the pandemic would impact and strain Kentucky's healthcare system and economy.

In response to many of the comments received and due to the uncertainty of the long-term effects of the ongoing pandemic, the Cabinet believes it would be unwise to implement substantive changes to the State Health Plan at this time. Accordingly, the Cabinet will remove the proposed substantive changes to the State Health Plan and all of the review criteria will remain unchanged from the prior version, "2018 Update to the 2017-2019 State Health Plan."

(a) Comment: Timothy Veno, President/CEO, LeadingAge Kentucky, provided testimony at the public hearing as follows per the written transcript:

"This is Tim Veno with LeadingAge Kentucky and I also sent in an after-hours request to be a part of the meeting. And I just want to take just a brief part of your morning and will be following up in more detail in writing, but I kind of want to echo what Chris Stevenson at Cedar Lake Lodge had said about this very important provision that has been in the State Health Plan for as long as I can remember.

The way that it's currently clarified to prohibit transfers from public ICF to a private ICF is an unnecessary change. Right now, the Cabinet has that discretion whether to agree or not agree to allow the transfer of a bed from a public to a private facility. It has been done in the past many years ago to respond to a crisis situation at one of the public ICF/IIDs; but to eliminate this as a provision leaves us and our members, Cedar Lake Lodge, Wendell Foster and others with significant waiting lists for their services.

The only excess capacity that we see right now of licensed beds versus occupancy is in the public facilities and this is a great way to help alleviate that demand and it's an unnecessary change given the Cabinet has that overall authority to agree or not agree.

It is within their discretion to do that. And we object to tying the hands of future administrators of that Cabinet and of need of these services to restrict their hands from allowing this to happen if there is a future emergency as we've seen in the past. I will be following up in writing and appreciate the opportunity to comment."

(b) Response: The Cabinet appreciates the comments from Tim Veno, LeadingAge Kentucky, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Heidi Schissler Lanham, Legal Director, Kentucky Protection and Advocacy, provided the following comments:

"Kentucky Protection and Advocacy (P&A) is an independent state agency that provides legally-based advocacy for individuals with disabilities throughout the Commonwealth of Kentucky, including individuals with intellectual and developmental disabilities (ID/DD). We write today in support of the proposed changes to provisions on Intermediate Care Facilities for Individuals with an Intellectual Disability (ICF-IID) beds in the State Health Plan at page 37.

We have been requesting this change since at least 2008 when the Cabinet and P&A executed a settlement agreement in *Michelle P. et al v. Birdwhistell, et al*. United States District Court, Eastern District of Kentucky, Frankfort Division, Civil Action #02-23-JMH.

ICFs-IID are long term care facilities, along with intermediate care facilities, nursing facilities, and nursing homes. KRS 216A.010(4). They serve individuals with intellectual and developmental disabilities. 42 CFR §440.150. Currently, Kentucky has 632 ICF-IID beds, 482 of which are public and 150 private. According to the most recently published

data in the Annual Kentucky Long Term Care Utilization and Service Report, the 2018 ending census for public beds was 248 and for private, 150.[1]

Title II of the Americans with Disabilities Act, as interpreted by the U.S. Supreme Court in *Olmstead v. L.C.*[2], requires states to provide services to individuals with disabilities in the most integrated setting appropriate to their needs—usually the community. This is one of the reasons why Kentucky continues to decrease the number of individuals in public ICF- IID beds. This is also the reason for the *Michelle P.* settlement agreement, referenced above, which put funding into and created community-based programs for the ID/DD population, including what is now called the Michelle P. waiver. The Agreement recognized that individuals would move out of public ICFs and included the provision '[t]he Defendants agree there will be no 'back-filling' of beds at publicly funded ICF/MRs [sic][3] as their populations are reduced' While the terms of the Settlement Agreement lasted until 2011, the language of the State Health Plan without the proposed change potentially runs afoul of the spirit of the agreement.

Another reason for the decrease in the use of public ICF-IID beds is a 2006 agreement between the U.S. Department of Justice (DOJ) and the Cabinet regarding Oakwood, a public ICF-IID, following a DOJ investigation. In 2006, the Cabinet agreed to make various programmatic changes at Oakwood and to decrease Oakwood's census with the target being 100 residents by September of 2011. While doing so, the Cabinet agreed to transfer 11 of Oakwood's public beds to Cedar Lake Lodge, a private ICF-IID. P&A unsuccessfully opposed the transfer through the Certificate of Need administrative hearing.[4] In the ensuing 14 years, no attempts have been made nor have any circumstance arisen requiring a need to transfer any additional public beds to Cedar Lake Lodge, or to the private ICF-IID, Wendell Foster. The proposed change would recognize this reality.

The move to serve individuals in the community is not only about the ADA, a Supreme Court mandate, or a DOJ settlement. Community placement is less expensive and integrates individuals with disabilities into the fabric of society. Many individuals with ID/DD, rather than being placed in an institution, receive services through one of the two 1915(c) Medicaid Home and Community Based wavier programs—Supports for Community Living (SCL) and Michelle P. Both programs provide all of the services that can be found in an ICF-IID except that Michelle P. does not provide residential services. The costs for both of these waivers is substantially less than the costs for an ICF-IID.[5]

It is also important to note that during the COVID-19 pandemic, there have been outbreaks in all of Kentucky's long-term care facilities, including ICFs-IID.[6]

Kentucky residents with ID/DD will be safer and healthier, and their cost of care less expensive if the new language in the State Health Plan is adopted. Kentucky will also be following the law and the recognizing that they are capable and worthy of community life.[7]"

(b) Response: The Cabinet appreciates the comments from Heidi Schissler Lanham, Kentucky Protection and Advocacy, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

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[1] https://chfs.ky.gov/agencies/ohda/surveyreports/2018LongTermCareReport.pdf , pp. 130-131.

[2] 527 U.S. 581 (1999)

[3] At that time, these institutions were called Intermediate Care Facilities for Mental Retardation.

[4] IN RE: Cedar Lake Lodge; (C/N #093-06-743(6)); Case No. AHB CON 06-1106

[5] The estimated annual average per capita cost for SCL which includes residential) is $83,539 and for ICF-IID is $329,289. https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver- list/81771

[6] https://www.courier-journal.com/story/news/local/2020/04/28/coronavirus-outbreak-kentuckys- hazelwood-center-worries-relatives/3034603001/

[7] *Olmstead v. L.C.* 527 U.S. 581, 600–01 (1999)

(2) Subject: Cardiac Catheterization Programs

(a) Comment: Jody Prather, M.D., Chief Strategy and Marketing Officer, Baptist Health, provided the following comments:

"Baptist is alarmed by the Cabinet's proposed change to the SHP criteria for establishing a fixed site diagnostic cardiac catheterization program. The Cabinet's proposed change to require that every comprehensive program rather than laboratory have performed at least 550 adult procedures in the last 12 months will lead to the proliferation of often needed programs. This change is nonsensical because some programs have up to eight laboratories. Therefore, existing programs with one laboratory will be treated the same as programs with multiple laboratories even though those programs could have double, triple, or octuple the capacity.

This change is especially unwarranted in light of the fact that the 2018 Annual Administrative Claims Data Report shows that diagnostic cardiac catheterization procedures have been relatively flat since 2016. Moreover, procedures are down significantly this year because of COVID-19. Therefore, Baptist strongly opposes the revision of the criteria for fixed site diagnostic cardiac catheterization."

(b) Response: The Cabinet appreciates the comments from Jody Prather, M.D., Baptist Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Sherri Craig, Market Vice President, Public Policy, CHI Saint Joseph Health, provided the following comments:

"Please accept the following comments on the proposed administrative regulation to establish the 2020-2022 State Health Plan from CHI Saint Joseph Health, one of the largest and most comprehensive health systems in the Commonwealth of Kentucky with 135 locations in 20 counties, including hospitals, physician groups, clinics, primary care centers, specialty institutes and home health agencies.

CHI Saint Joseph Health fully supports the revised language on page 39 to clarify that the base requirement to add a fixed site diagnostic cardiac catheterization program at a hospital would be calculated on an existing program's utilization, rather than a specific laboratory's utilization. This is because, under current rules, a program may add laboratories once licensed, essentially holding any other hospital in the planning area to a standard it may never be able to reach.

Additionally, we recommend amending criterion 7 for approval of comprehensive cardiac catheterization 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. The development of these cardiovascular networks is crucial to meet access and demand for cardiac services across the Commonwealth especially in rural areas where distance and travel to a comprehensive center is a burden for the patient and their family.

Recommended language for criterion 7:

> Notwithstanding criteria 1, 2, 3, 4, 5, and 6, an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this Plan if:
>
> a. The applicant is a licensed Kentucky acute care (non-critical access) hospital affiliated with the cardiology program of the primary teaching facility of the University of Kentucky or the University of Louisville (collectively "Kentucky academic medical center") ***or collaborating tertiary hospital that has an active comprehensive cardiac surgical program (including open-heart surgery) within the facility*** through a formal affiliation in the form of an agreement or a

contract in place for at least ~~two (2) years~~ ***one (1) year*** and specifically focusing on improving cardiology care in the service area or county of the applicant hospital;

b. The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of a Kentucky academic medical center ***or collaborating tertiary hospital that has an active comprehensive cardiac surgical program (including open-heart surgery) within the facility;***

c. The applicant hospital is located within ~~fifty (50)~~ ***seventy five (75)*** highway miles of the primary teaching facility of a Kentucky academic medical center ***or collaborating tertiary hospital that has an active comprehensive cardiac surgical program (including open-heart surgery) within the facility;***

d. The applicant hospital is located in a county that does not have an existing cardiac catheterization service and has a population greater than 30,000; and

e. The applicant hospital has a minimum of ~~20,000~~ ***18,000*** emergency department encounters on an annualized basis."

(b) Response: The Cabinet appreciates the comments from Sherri Craig, Market Vice President, Public Policy, CHI Saint Joseph Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Karen Hartman, President and CEO, and Lorraine Buck, Vice President, Corazon, Inc., submitted the following comments:

"Please accept this letter and accompanying support documents addressing our comments to the proposed 2020-2022 Kentucky State Health Plan, Regulation Number: 900 KAR 5:020; Chapter IV: Diagnostic and Therapeutic Equipment and Procedures; Section A. Cardiac Catheterization Service, page 38.

Corazon appreciates this opportunity and is committed to the health and welfare of patients. We strongly support and advocate therapeutic (PCI) services with off-site surgical back-up for centers that meet requirements, not only in the State of Kentucky, but across the United States.

Corazon has intimately worked with other states' regulatory offices, specifically the states of Michigan and Pennsylvania. …

Corazon, Inc. has provided over 20 years of service to hospitals and health systems across the country, including Kentucky. Corazon offerings are within the cardiovascular, neuroscience and orthopedic specialties providing consulting, accreditation, recruitment,

and interim services. Corazon's team of service line experts provides the strategic, clinical, operational, market, and financial expertise necessary to develop a truly outstanding specialty program, regardless of existing scope of services.

Corazon has extensive experience in working with hospital coalitions and state regulatory agencies as they work to understand how to implement the necessary structure and processes for hospitals to provide PCI without Open Heart Surgery. Corazon has kept quality of service and patient safety as the corner-stone in any state regulation update. For example, around 5 years ago in Pennsylvania, Corazon created the hospital consortium to address the PA Department of Health regulations and worked with the state and hospital leadership to develop the exemption in place today for hospitals having PCI without OHS On-site services. Corazon has provided this service in Michigan, Georgia, and New Jersey as well.

Corazon is recognized as a formal accrediting body in Pennsylvania, Michigan, and Georgia and has served to drive regulatory changes and identify key requirements to ensure program quality, not only in these three states, but nationally (e.g., Florida, Kentucky, etc.). As of today, Corazon is a national leader in accreditation services of Cardiac Cath/PCI services and the only accrediting body for OHS in the country, whether mandated by a state or a hospital elects the accreditation.

In 2011, Corazon was engaged by Our Lady of Bellefonte Hospital (OLBH), located in Ashland, Kentucky, to assist with and provide CON support so the facility could offer 'elective' therapeutic cardiac catheterization services (also referred to as PCI). Prior to Corazon's involvement, OLBH offered 'primary' PCI, as this was permitted in Kentucky under the auspice of the state 'pilot project.' This allowed the hospital to provide primary cardiac intervention for those patients with an acute myocardial infarction (acute heart attack) up until recently when Bon Secours Health System announced that it was exiting acute and outpatient care in the Ashland and Tri-state communities, resulting in the closure of OLBH.

Prior to and during the KY CON process, Our Lady of Bellefonte Hospital extended clinical and financial resources in an effort to provide care to this selective patient population (AMI) and sent patients having other coronary artery diseases outside their hospital walls. The transfer and travel burden of these patients could have been avoided, as well additional costs to the patients, had Kentucky allowed for the simultaneous acceptance of Our Lady of Bellefonte caring for both 'elective' and 'primary' patients in need of treatment for cardiovascular disease.

Upon Our Lady of Bellefonte Hospital's CON approval to offer expanded cardiovascular care to ALL patients, the hospital was able to pursue and achieve formal PCI accreditation from Corazon. Corazon's accreditation offers ongoing quality monitoring and support to ensure that Our Lady of Bellefonte Hospital, and any Corazon-accredited hospital, meets and/or exceeds 'best-practice' standards and adherence to the most recent societal guidelines for cardiovascular care while keeping patients close to home.

Health Plan Background: The current Kentucky Health Plan Language for cardiac catheterization and therapeutic (PCI) without open heart surgery on-site needs revisions to stay on track with technology and practice changes. Healthcare facilities need to be able to offer life-saving, advanced cardiac services to their communities and perform these services with the highest quality of care and in a cost- effective manner. **PCI is considered to be the 'gold standard' of care for patients presenting with acute myocardial infarction (AMI or heart attack) and is proven through many research studies to be accepted as the 'best-practice' approach**. According to the *American College of Cardiology/AHA Guidelines* for the management of patients with ST- Elevation Myocardial Infarction (2004), 'All STEMI patients should undergo rapid evaluation for reperfusion therapy and have a reperfusion strategy implemented promptly after contact with the medical system. Reperfusion may come in the form of fibrinolytic or PCI. Higher-risk patients report later to the hospital and may respond better to PCI than to fibrinolytic agents. Second, shorter door-to-balloon time may be a surrogate for better quality care and adherence to treatment guidelines. The Task Force on the Management of Acute Myocardial Infarction of the European Society of Cardiology and the Committee both recommend a target medical contact – or door-to-balloon time of less than 90 minutes.'

The majority of states in the country have limited or no regulations surrounding programmatic development of diagnostic cardiac cath and PCI services. States have forgone the CON process for these services and others have minimized the tiered process of having to perform initial diagnostic caths prior to therapeutic procedure services offered (State of the Union Map). States have realized that relying on patients to be transferred from a non-PCI capable facility to a PCI facility can cause unnecessary delays in care and lead to life and death situations. This has caused states to implement alternative plans to afford this access to care to patients (Appendix A).

Many states have recognized the ongoing changes in technology and clinical practice. Because of this, they have moved forward in appropriately changing state plan regulations in order to address patient care demand and access to community care, offering much needed, advanced cardiac procedures, which will ultimately help to save lives.

Corazon Recommendation: It is Corazon's belief that the Cabinet for Health and Family Service's highest priority should be to protect the health, safety, and welfare of its citizens. This should include reasonable access to life-saving Cardiac Diagnostic and PCI procedures. 'Therefore, it is Corazon's recommendation that the Kentucky State Health Plan be amended to allow hospitals to apply for a CON to establish diagnostic and therapeutic cardiac catheterization services in a single proposal, subject to meeting standards that we suggest below. Consequently, Corazon has provided changes to the existing language of the Plan related to catheterization services. Our recommendations do not apply to all of the existing criteria; for example, no changes are suggested to the definition below.'

Cardiac Catheterization Service: ***Definition.*** ***'***Cardiac Catheterization' is a diagnostic or therapeutic procedure in which a catheter is introduced into a large vein or artery, usually

of an arm or a leg, and threaded through the circulatory system to the heart. To determine the number of cardiac catheterization procedures performed, each administrative claims record submitted pursuant to KRS 216.2920 – 216.2929 and 900 KAR 7:030 is examined to determine if it contains procedure codes indicating diagnostic catheterization or therapeutic catheterizations as defined below. Inpatient Hospital Discharge records are examined for ICD-10 Procedure codes as published in the most recent Professional Edition ICD-10-CM Manual for Hospitals Volume 3, while Outpatient Services Records are examined for CPT Procedure codes as published in the most recent Professional Edition Current Procedural Terminology Manual. As published in the *Annual Administrative Claims Data Report – Cardiac Catheterization,* diagnostic includes a count of the number of administrative claims records where the record included a Diagnostic Code regardless of the presence of any additional Therapeutic code. Therapeutic includes a count of the number of administrative claims records where the record included a Therapeutic Code regardless of the presence of any additional Diagnostic code.

'Diagnostic' cardiac catheterization means providing diagnostic only cardiac catheterizations on an organized, regular basis, in a laboratory. The term includes the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic).

'Therapeutic' cardiac catheterization means a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart to treat and resolve anatomical or physiological problems in the heart. These procedures are intended primarily for the treatment of cardiac disease. The term includes percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PCTA), atherectomy, and stent. The use of clot-dissolving infusion drugs approved by the FDA such as Streptokinase and TPA does not constitute the provision of therapeutic cardiac catheterization.

With regard to cardiac catheterization services, the term 'Laboratory' means each dedicated room within a fixed-site facility that is individually equipped and staffed for the purposes of performing cardiac catheterizations.

With regard to cardiac catheterization services, the 'Planning Area' shall be comprised of the county of the proposed cardiac catheterization program and all contiguous counties.

Review Criteria Corazon Suggested Changes to Current KY Language [shown underlined and italicized].

An application proposing to provide cardiac catheterization services shall be consistent with this Plan if the following criteria are met:

1. For all cardiac catheterization laboratories, the applicant shall maintain a utilization review program (including record keeping) related to medical necessity, quality, mortality, morbidity, number of cardiac catheterizations that require repetition due to

inability to read the data, and other considerations generally accepted as appropriate for review.

2. For all cardiac catheterization laboratories, the applicant shall document that the most recent national guidelines as established by the Ad Hoc Task Force on Cardiac Catheterization of the American College of Cardiology/American Heart Association and published in ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories will be followed. This report sets guidelines for administration, space, equipment, personnel, and working arrangements for diagnostic and therapeutic cardiac catheterization laboratories;

3. For applicants proposing fixed site diagnostic cardiac catheterization only:
   a. The applicant is licensed by the Cabinet for Health and Family Services, Office of Inspector General as an acute care hospital pursuant to 902 KAR 20:016.

   b. 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 are shall have performed at least 250 adult diagnostic procedures in the last twelve (12) month reporting period. Each existing fixed-site comprehensive program [laboratory: laboratory is replaced with PROGRAM] (diagnostic and therapeutic) shall have performed at least 550 adult procedures in the last twelve (12) month reporting period;
   [Corazon Agrees with the proposed language change as stated above]

   c. The total projected number of adult diagnostic catheterizations in the planning area shall exceed the total existing adult procedures by at least 250 procedures by the end of the third year of operation.

      i. The total projected number of adult procedures will be based on the adult diagnostic cardiac catheterization use rate or the Commonwealth of Kentucky for the most recent twelve (12) month period for which data are published in the Administrative Claims Data Report – Cardiac Catheterization applied to the projected planning area population three (3) years in the future from the date the application was filed; and

      ii. The number of diagnostic cardiac catheterization procedures performed by existing programs, according to the most recent edition of the Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization, will be subtracted from the total projected diagnostic procedures for the planning area. If there are approved fixed-site laboratories not included in the most recently published Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization, an additional 250 procedures will be subtracted from the total for each fixed-site laboratory; and *the market is developed by using the hospitals' primary and secondary markets, utilizing Kentucky Hospital Association data, and determining volume projections using market share projections.*

***Rationale**: Hospital primary and secondary markets are defined by tracing the patient origin of prior admissions or discharges. Other considerations in defining a hospitals specific service area include: referral patterns, physician locations, competitor landscape, and growth opportunities. Typically, at least 90% of patient admissions/discharges originate in the hospital-specific service area. Additionally, the available volume in the service area should be determined by utilizing claims-based data reported in the Kentucky Hospital Association inpatient and outpatient discharge data (rather than self-reported volume). The Kentucky IPOP is submitted, collected, and edited by hospitals as required by statute and administrative regulation, to the Commonwealth of Kentucky.*

d. The applicant has established a cardiology program as evidenced by the availability of at least two (2) board certified cardiologists with medical staff privileges at the applicant's hospital;

4. An applicant that is licensed to provide fixed site diagnostic cardiac catheterizations proposing to expand its services to also provide fixed site therapeutic cardiac catheterizations limited to primary (i.e., emergency) and elective Percutaneous Coronary Intervention (PCI) services *or an applicant that is proposing to begin both diagnostic and therapeutic catheterization (PCI, primary and elective)* shall meet the following criteria:

***Rationale**: Initiating diagnostic Catheterization and Therapeutic Cath (PCI) is considered the 'Gold' standard of care. Requiring hospitals to initiate services with Diagnostic Cath only will have a negative impact on the hospitals and community. Examples include:*

- *Hospitals not having the ability to provide 'life-saving' treatment for patients who present to hospitals emergency department. Timely care, in less than 60 minutes, is imperative to having a positive impact on the patient's life. Patients would need to be transferred to a hospital offering this service, which may not result in the best patient outcome;*
- *Financial hardships and stress placed on patients and families who have to travel extended distances for advanced procedures;*
- *Hospital never reaching diagnostic volumes due to patients requiring PCI will bypass this hospital; the standard today is to complete the cath and PCI together (namely, Cath possible) so the patient does not need to have multiple invasive procedures;*
- *Increasing costs of healthcare as procedures are being performed at two facilities versus one, and patient transfer costs.*

Permitting hospitals to perform both diagnostic and therapeutic procedures (PCI) without open heart surgery on-site, once meeting defined requirements, is supported by the following nationally recognized societies:

- *2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac*

Catheterization Laboratory Standards Update,

- *2014 Society for Cardiovascular Angiography and Interventions/American College of Cardiology/American Heart Association Expert Consensus Document Update on Percutaneous Coronary Intervention Without On-site Surgical Backup, and*
- *2016 SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory*

a. The applicant shall be an existing licensed Kentucky acute care hospital;

b. The applicant shall have performed, according to the most recent edition of the Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization, an average of at least 200 annual diagnostic cardiac catheterization procedures during the previous two (2) years;

c. The proposed service shall be staffed with the following:
   i. Experienced nursing and technical laboratory staff with training in interventional laboratories who are comfortable treating acutely ill patients with hemodynamic and electrical instability;
   ii. Coronary care unit nursing staff experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of temporary pacemaker, and management of intra-aortic balloon pump (IABP), management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia, and access site complications;
   iii. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary;
   iv. A program director, whether located on-site or based at a facility with a comprehensive cardiac surgical program, who shall have performed at least 500 career PCI procedures over a life time, have performed a minimum of 150 PCI procedures in the previous year, and be board certified by the American Board of Internal Medicine in interventional cardiology;
   v. Operators that shall have American Board of Internal Medicine (ABIM) board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams; and
   vi. Interventional cardiologists who shall have performed a minimum of fifty (50) coronary intervention procedures per year, averaged over a two (2) year period, to maintain competency.

d. The primary PCI services shall be available on a continuous twenty-four (24) hour per day basis;

e. Support services including respiratory care, blood bank, intensive care, advanced imaging, and nephrology consultation with access to dialysis shall be available;

f. The application shall contain a current, signed agreement for emergency transfer of patients to a collaborating tertiary hospital that has an active comprehensive cardiac surgical program (including open-heart surgery) within the facility. This agreement shall commit the collaborating tertiary facility to the following:
    i. Provide continuous twenty-four (24) hours per day availability of consultation to the physician and nursing staff of the applicant's participating hospital in the care of patients that are candidates for or have received primary or elective angioplasty;
    ii. Establish cardiopulmonary bypass on emergency transfer patients within 120 minutes of an urgent referral;
    iii. Develop and participate in a joint performance improvement program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses, and technicians from the staffs of both the applicant's participating hospital and the collaborating facility) providing patient care and focusing on patient outcomes;
    iv. Develop and participate in joint in-service education programs for all staff (including physicians, nurses, and technicians) at the collaborating hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the performance improvement program; and
    v. Collaborate with the applicant's participating hospital to undergo peer review of the first 150 therapeutic cardiac catheterization procedures through the Joint Performance Improvement Committee. A peer review shall be conducted for all patients who were either transferred to the tertiary hospital or experienced an adverse outcome as defined by the ACC.

g. The applicant shall maintain a cardiac catheterization laboratory equipped with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. Additionally, the applicant and the collaborating tertiary facility shall have an image transfer system in place with capabilities for immediate consultation between the applicant's cardiologist and the collaborating facility's cardiothoracic surgeon or interventional cardiologist;

h. The applicant shall maintain an inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. The applicant shall have access to intravascular ultrasound and fractional flow reserve;

i. The applicant shall maintain an ST-segment elevation myocardial infarction (STEMI) system of care in accordance with the most recent SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup;

j. The applicant shall maintain an ongoing program for data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case

review, including without limitation tracking door-to-balloon times and other metrics set forth in the most recent SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup;

k. The applicant shall participate in the American College of Cardiology National Cardiovascular Data Registry;

l. The applicant shall have an agreement with an ACLS-capable ambulance service stating that the service will respond to a call from that facility in no greater than thirty (30) minutes and arrive at the collaborating facility within sixty (60) minutes of the decision to declare the need for emergency surgery. The ambulance service shall also meet all American College of Cardiology (ACC) requirements for transporting heart patients and provide evidence that EMS or air transport has the capability to transport a patient with a balloon pump;

m. The applicant shall obtain consent from each patient that informs the patient that the PCI is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent shall include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists; and

n. The PCI program shall project at least 200 annual PCIs and that each interventional cardiologist shall perform an average of at least fifty (50) annual coronary intervention procedures during the second year of operation;

o. *Programs will have a national firm provide Cath/PCI accreditation; if volume is less than 200 cases annually, accreditation would be performed annually. For all others, accreditation would be performed biannually.*

***Rationale**: It is generally accepted that a direct relationship exists between procedural volume and outcomes. However, much of the medical literature has looked at volume as a measure of quality. Although volume is an important indicator of quality, other indicators such as safety and quality outcomes are even more important than volume for measurement. The latest ACCF/AHA/SCAI 2013 Clinical Competence Statement cautions against overemphasis on specific volume recommendations, recognizing that volume are just one of many factors related to clinical outcomes. Additionally, according to the Agency for Healthcare Research and Quality (AHRQ), the volume-outcome relationship may not hold over time as providers become more experienced or as technology changes. Requiring accreditation by an outside third party ensures that all program requirements are met and consistently followed. Therefore, programs should have a national firm provide Cath/PCI accreditation; if volume is less than 200 cases annually and should be an accreditation that's performed annually. For all others, accreditation would be performed biannually.*

5. For an applicant that is licensed to provide fixed site diagnostic cardiac catheterization services proposing to expand its services to also provide therapeutic catheterizations beyond PCI only, the applicant shall also document that:

a. Training for percutaneous transluminal coronary angioplasty (PTCA) will follow the guidelines set forth in the Bethesda Conference on Adult Cardiology Training (Journal of the American College of Cardiology, 1986; 7: 1191-218), as revised, which require extra training beyond the two (2) years for clinical cardiology; and

b. Each physician is projected to perform at least seventy-five 75 successful angioplasties per year with acceptable mortality and morbidity in patients who warrant the procedure;

6. For applicants proposing a pediatric cardiac catheterization laboratory, the facility shall also offer a pediatric cardiac surgical program and a Level IV neonatal intensive care unit.

7. Notwithstanding criteria 1, 2, 3, 4, 5, and 6, an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this plan if:

   a. The applicant is a licensed Kentucky acute care (non-critical access) hospital affiliated with the cardiology program of the primary teaching facility of the University of Kentucky or the University of Louisville (collectively 'Kentucky academic medical center') through a formal affiliation in the form of an agreement or a contract in place for at least two (2) years and specifically focusing on improving cardiology care in the service area or country of the applicant hospital;

   b. The medical director and the cardiologists staffing the applicants proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of a Kentucky academic medical center;

   c. The applicant hospital is located within fifty (50) highway miles of the primary teaching facility of a Kentucky academic medical center;

   d. The applicant hospital is located in a county that does not have an existing cardiac catheterization service and has a population greater than 30,000 and

   e. The applicant hospital has a minimum of 20,000 emergency department encounters on an annualized basis;

8. An application to establish a mobile cardiac catheterization service shall not be approved under this plan; and

9. Notwithstanding criteria 1,2,3,4,5,6,7 and 8, an application to establish a fixed-site diagnostic cardiac catheterization service shall be consistent with this plan if the following criteria are met:

   a. The applicant is an acute care hospital that is providing diagnostic cardiac

catheterization with intermittent equipment through a mobile license; and

b. The applicant is proposing to replace the mobile service at its hospital with a fixed-site, diagnostic cardiac catheterization service."

(b) Response: The Cabinet appreciates the comments from Karen Hartman, President and CEO and Lorraine Buck, Vice President, Corazon, Inc., regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(3) Subject: Ambulatory Surgical Centers

(a) Comment: Daniel Winkler, Vice President – Operations, Southern Kentucky Surgicenter, LLC, provided the following comments:

"Please accept these comments on behalf of Southern Kentucky Surgicenter, LLC ('Surgicenter') regarding 900 KAR 5:020 and the proposed 2020-2022 Kentucky State Health Plan ('SHP'). Surgicenter is a freestanding licensed ambulatory surgery center located in Bowling Green, Kentucky. Surgicenter opposes the proposed changes to the ambulatory surgery center ('ASC') criteria, which create a broad exemption for certain hospitals from the application of the utilization criteria currently in the SHP. We believe the proposed changes create an exception that does not take into account the current utilization and existing capacity for such services and, therefore, could harm existing facilities and could result in increased costs to the health care delivery system. Moreover, the new criteria is unfair in that it only provides an exception for hospitals not for other free standing surgery health care providers.

The Kentucky State Health Plan is the state health planning document created pursuant to KRS 216B.040. Consistent with KRS Chapter 216B, the purpose of the State Health Plan is to carry out the Legislative intent behind CON law to avoid the proliferation of unnecessary health care services and related costs. To accomplish that goal, the SHP has historically contained a specific formula that must be met, except in very limited circumstances, before a CON is granted to establish a new ASC. The formula takes into account the number of surgeries performed in the proposed service area and the number of existing hospital and ASC operating rooms in the area. This formula is designed to ensure that the existing operating rooms are being sufficiently utilized before a new ASC with additional operating rooms is permitted. This is all consistent with Kentucky's CON law.

900 KAR 5:020, published by Cabinet on April 7, 2020, contains amendments to the ASC criteria in the SHP which ignore the utilization formula. If adopted, this new ASC criteria would create an exception that allows a few hospitals to establish ambulatory surgery centers without meeting any utilization requirements. The amendment exempts hospitals

from almost all of the usual SHP criteria required to obtain a CON to establish an ASC (including the utilization formula described above) if the proposed new ASC:

- Is majority-owned by the hospital;
- Is in the same county as the hospital;
- Is in a county that has a population over 30,000; and
- The hospital has achieved a sufficient 'star rating' on the Hospital Compare website.

As noted above, the stated purpose of CON is to prevent proliferation of unnecessary health care services that results in costly duplication and underuse. (KRS 216B.010.) Establishing new ASCs without regard to the utilization formula in the current SHP goes against that stated purpose. If the existing operating rooms in the area of the new ASC are not being sufficiently utilized already, then adding more operating rooms creates duplication and further underutilization. Further, while additional ASCs may increase the supply of operating rooms in counties that qualify under the new proposed criteria, it will actually cause an overall decrease in access to a broader range of other healthcare services by draining outpatient surgery revenue from hospitals and other providers that rely on this revenue to provide other services. This would lead to the weakening of hospitals and ambulatory surgery centers that are already financially strained by the effects of Covid-19. Ambulatory surgery centers like ours and hospitals have already been weakened by the ban on elective surgeries during the pandemic. Adding ASCs where there is no need and putting a further financial strain on existing hospitals and ambulatory surgery centers that depend on revenue from their operating rooms is contrary to the good health planning, especially in a post Covid-19 world.

Thank you for consideration of these comments."

(b) Response: The Cabinet appreciates the comments from Daniel Winkler, Southern Kentucky Surgicenter, LLC, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Phillip Wheeler, State Senator, 31st District, provided the following comments:

"I am writing to submit comments on 900 KAR 5:020, which incorporates proposed changes to the Kentucky State Health Plan, and to voice my opposition to the changes in the Plan related to Ambulatory Surgery Centers (ASCs). I believe that these changes are contrary to the express legislative purpose of the Kentucky certificate of need (CON) system, and will actually result in a decrease of key available health services in my district and other rural counties throughout the state which have more than one hospital, and may in fact constitute unconstitutional special legislation.

The stated purpose of Kentucky's certificate of need (CON) system in K.R.S. 216B.010 is to avoid proliferation of unnecessary health care facilities because it results in costly duplication and underuse of existing facilities. The proposed changes to the State Health Plan for ASCs would permit the establishment of a new ASC without meeting the operating room utilization formula that is required by the current version of the Plan. By ignoring the utilization formula, the proposed changes are directly contrary to the express statutory purposes of the CON system and will result in underuse of existing surgical facilities.

As the ongoing COVID-19 pandemic has acutely illustrated in recent weeks, hospitals constitute vital pieces of infrastructure for our communities. That is not only true in terms of health and wellness, but in rural Eastern Kentucky, where we have experienced significant coal industry job losses, hospitals represent important economic engines as well.

Hospitals derive substantial revenue from outpatient surgery. They need this surgery revenue to be able to continue to provide other services that are less profitable, but simultaneously important for their communities. In my district, Pikeville Medical Center provides many important specialty services that are not available elsewhere in the region.

If a new ASC is permitted in the Pikeville market, it will drain off surgery revenue from Pikeville Medical Center, which will necessarily result in the hospital having to curtail other specialty service offerings. This will have an adverse effect on our low-income population, because patients and their families will have to endure traveling long distances outside the region and, in some cases, outside the state, to find alternate sources of care. Some will not be able to make the journey and will go without care, thereby increasing mortality and morbidity. For those who do travel outside the region for care, it represents an exodus of health care spending from our community, thereby negatively affecting the local economy. This same phenomenon is likely true in other rural areas around the state.

This may not be true for more urban areas of the Commonwealth, but the proposed change to the State Health Plan ASC criteria is applicable to counties with a population count above 30,000. This could easily be changed to accommodate ASCs in urban areas without damaging the vital hospital infrastructure in rural areas by simply increasing the population requirement to 75,000 or 100,000.

Proponents of ASCs often cite their ability to provide surgery services in a lower cost environment. Lowering costs for any health care service is certainly laudable, but not at the expense of patient access to other vital health care services that hospitals provide. Further, ASCs have a tendency to ‘cherry-pick’ the higher paying surgical cases covered by private health insurance, leaving the lower paying Medicare and Medicaid surgeries to hospitals. Nonprofit and most other hospitals provide millions of dollars of charity care in our state each year. ASCs typically provide much less, if any at all.

Those in favor of the proposed State Health Plan changes might argue that the changes are not damaging to hospitals because the new language which would allow CON applicants to avoid the utilization formula only applies to applications for new ASCs that are majority-owned by a hospital. However, this ignores the geographical reality in rural counties, particularly the larger ones, with multiple hospitals. In such counties, there are usually several smaller towns or communities within the county that are separated by several miles. There may be one hospital in Community A and another hospital in Community B within the same rural county. Thus, the hospital from Community A could place a new ASC on the doorstep of the hospital in Community B; and, thereby, have the same negative effect on Community B's hospital's surgery revenue as described above.

It is not necessary for the state to permit this in order to pursue the cost-lowering goals of ASCs. A change to the proposed language which would require the new ASC to be placed on or very near the campus of the sponsoring hospital would eliminate the damage to the second hospital while allowing the sponsoring hospital to achieve its cost-reduction goals. Further, restricting the ASC location to, or very near, the sponsoring hospital's campus means that any underutilization of operating rooms caused by the new ASC would most likely occur in the sponsoring hospital's operating rooms; and, therefore, generally be self-inflicted underutilization. This situation would represent a more rational basis for ignoring the utilization formula in the current State Health Plan. Again, this may not be as much of a concern in the urban areas of the state where a county generally consists of one unified community, but it should be recognized that urban and rural areas are not the same and that hospital infrastructure in rural communities needs to be preserved.

Finally, I fear that the currently proposed ASC changes to the State Health Plan may represent a plan designed to benefit a few specific hospitals in the state; and, as such, may represent prohibited special legislation. Even if that is not actually the case, it raises the specter of potentially lengthy and costly litigation for the state and medical providers. This is money that could be better spent caring for sick and injured Kentuckians and expanding our economy."

(b) Response: The Cabinet appreciates the comments from Phillip Wheeler, State Senator, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Dr. Mark Newman, Executive Vice President for Health Affairs, University of Kentucky HealthCare, provided the following comments:

"University of Kentucky Hospital is writing to comment on the proposed changes in the Ambulatory Surgical Center ('ASC') review criteria in the 2020-2022 Kentucky State Health Plan. Specifically, we are opposed to the proposed ASC Criterion 7

contained on page 54.

We have been a longstanding, strong supporter of the Certificate of Need program and policies and the State Health Plan. We believe that significant changes in the State Health Plan should be based upon sound health planning and a data-driven analysis of need throughout the Commonwealth.

Before the Cabinet moves forward, we propose that sound health planning analysis should include answering three fundamental questions: (1) Is there a need for additional ASCs? (2) If so, how many additional ASCs should there be? and (3) Where are they needed?

Specifically, as the Cabinet considers this change in policy, we do not agree that the answers to any of these questions should be tied to the CMS Star ratings of the hospital. CMS Start ratings are a flawed system for quantifying the quality of care delivered in our Commonwealth's hospitals.

Larger hospitals, teaching hospitals, and those serving many low-income patients disproportionately receive lower ratings in the CMS methodology. Changes in the methodology since 2015 seem to magnify that disproportionate impact. A relatively small number of measures that were highly weighted had a disproportionate negative impact on our rating.

The University of Kentucky Hospital (AB Chandler) ranks #1 in Kentucky in the U.S. News Rankings and in the top tier of academic health centers as rated by our peer association Vizient when it comes to quality measures. U.S. News uses CMS *and other data* to arrive at its ranking. U.S. News follows a methodology that adjusts for high-risk, complex patient populations, whereas CMS does has little risk adjustment in its ratings.

We understand that discussion about how to rate quality is the subject of much debate and we would welcome a discussion about how to track and report quality provided by hospitals and by ASCs (though we would propose very different methodologies based on these very different settings).

Finally for these reasons, not only would the proposed changes unjustifiably favor hospitals with high Star ratings, totally unrelated to the ability to operate an ASC or the need for an ASC, the proposed criteria also unfairly discriminate against teaching hospitals/academic medical centers.

In conclusion, we are opposed to the proposed ASC Review Criterion 7 and respectfully request that the Cabinet delete it from the proposed 2020-2022 State Health Plan. In the alternative, if the Cabinet does choose to adopt some version of Criterion 7, we ask that it be amended to eliminate the Star rating proposal. Alternatively, the Cabinet could choose to carve the state university teaching hospitals out of the CMS Star Rating criteria and allow them to still be included in

the group of hospitals that would be authorized to establish an ASC.

Thank you for your consideration of these comments. Please let me know if you have any questions or would like to discuss this further."

(b) Response: The Cabinet appreciates the comments from Dr. Mark Newman, University of Kentucky Health Care, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Daniel Riggs, Group President, Surgical Care Affiliates, provided the following comments:

"On behalf of Surgical Care Affiliates (SCA), I am pleased to submit these comments supporting the proposed changes to the 2020-2022 State Health Plan.

Throughout Kentucky, SCA's ambulatory surgery centers (ASCs) are providing high-quality, cost-effective surgical care. We operate four multi-specialty surgery centers within the state, Surgecenter of Louisville, Premier Surgery Center of Louisville, Lexington Surgery Center, and Owensboro Surgery Center. All four of our ASCs in Kentucky specialize in outpatient surgery for both pediatric and adult patients. In 2019, we performed nearly 27,000 surgeries including general, colorectal, ENT, oral, plastic, podiatry, ophthalmology, urology and pain management procedures.

Our facilities welcome independent and employed physicians who appreciate the quality and efficiency of care of an ASC setting. Our partnerships with University of Kentucky Healthcare and Owensboro Health allow us to provide exceptional care for patients within those geographies and help advance our continued mission to improve healthcare in America.

SCA supports the proposed change to the 2020-2022 State Health Plan as filed on April 3, 2020 that revises the language of the review criteria to enable a Kentucky-licensed acute care hospital to establish an ambulatory surgical center in the same county as the hospital. We believe this narrow amendment to the review criteria that expands patient access to ASCs will improve the efficiency of the health system and reduce the cost of health care to Kentuckians. While we support the overall effort to measure quality performance for eligible hospitals, we feel the Centers for Medicare and Medicaid Services Hospital Compare is not the most equitable rating system to determine quality of care.

We respectfully request that if the review criteria allowing for Certificate of Need waivers is substantially alerted beyond the revisions noticed in the 2020-2022 State Health Plan filed on April 3, 2020 that additional time is granted for public comment or a formal review is conducted by the cabinet.

I would like to thank you again for this opportunity to provide SCA's comments and recommendations. If SCA can be of a resource to you, please do not hesitate to call on us."

(b) Response: The Cabinet appreciates the comments from Daniel Riggs, Group President, Surgical Care Affiliates, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Randall S. Strause, Strause Law Group, provided the following comments:

"Thank you for the opportunity to submit this comment concerning 900 KAR 5:020 and the *2020 – 2022 State Health Plan* (April 2020) incorporated therein by reference. The comment is submitted in regard to the State Health Plan review criteria for ambulatory surgical centers (hereinafter 'ASC'). Specifically, we respectfully propose revisions to Review Criteria 1 and 5 as currently drafted.

Review Criteria 1

Review Criteria 1 currently provides for the establishment of an ASC if the:

> Overall inpatient and outpatient surgical utilization in hospitals and ASCs is at least eighty-five (85) percent in the planning area as computed from the most recent editions of the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Service Report*. With regard to ambulatory surgical services, the planning area shall be comprised of the county of the proposed center and all contiguous Kentucky counties.

According to the Division of Certificate of Need online application database, it does not appear that an applicant has successful advanced an application to establish an ASC under this Review Criteria in over ten (10) years. The threshold for establishing an ASC in a particular county is unreasonably high considering that both hospital inpatient and outpatient surgical utilization is considered in the calculation as well as such utilization in all contiguous counties. The current methodology prevents an ASC from being established in counties where no surgical procedures have historically been performed as long as surgical procedures have been performed in the planning area. Competition traditionally promotes the provision of higher quality services. According to the latest licensed directory of licensed ambulatory surgical centers published June 22, 2020, ASCs are located in just fourteen (14) of one hundred twenty (120) Kentucky counties. See, Attachment 1. Out of fifteen (15) Area Development Districts (hereinafter 'ADD') within the Commonwealth, four (4) ADDs do not have an ASC, eight (8) ADDs have only one (1) ASC, and three (3) ADDs have two (2) ASCs. Notably, there is an absence of ASCs in the eastern Kentucky region.

We respectfully propose that Review Criteria 1 be revised as follows

1. *Notwithstanding criteria 4, 5, 6, 7, and 8, an application to establish an ambulatory surgical center shall be consistent with this Plan if the following conditions are met:*

    a. *The applicant is a physician or physician group, 100% owned by physicians, which have been organized and practicing in Kentucky for a period of ten (10) years prior to the date the application was submitted;*

    b. *The proposed ambulatory surgical center is located in the county where the private office is currently located;*

    c. *No outpatient ambulatory surgical center has been established in the county;*

    d. *Only one (1) ASC shall be established by the applicant; and*

    e. *The applicant documents that the proposed ASC shall be accredited within twelve (12) months of licensure by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), The Joint Commission (TJC), or another accreditation organization approved by the United States Centers for Medicare and Medicaid Services;*

Review Criteria 5

Review Criteria 5 sets forth the specific criteria for an applicant to establish an ASC limited to ophthalmic surgery procedures. We respectfully submit that the condition set forth in subsection 5.c., as outlined in the following, should be eliminated as a condition to establish an ASC limited to ophthalmic surgery procedures.

5. c. The applicant documents that prior to March 30, 2016, it has invested no less than $300,000.00 in advanced ophthalmic laser technology;

First, the March 30, 2016 date is completely arbitrary and not rationally or reasonably related to any type of healthcare metric, need for ophthalmic ambulatory surgical services, nor the ability to provide quality of services. Additionally, this arbitrary date creates a barrier for applicants to establish an ASC because it passed more than four (4) years ago and prevents future applicants who did not have the foresight to acquire advanced laser technology by March 30, 2016 from establishing an ASC limited to ophthalmic surgery procedures in the future. No other ASC review criteria contains an arbitrary requirement of investment in healthcare technology by a certain date, much less a date that passed more than four (4) years ago.

Second, the requirement that an applicant document an investment of no less than $300,000 in advanced ophthalmic laser technology is completely arbitrary as well as there is no relationship between this specific monetary figure and any type of healthcare metric,

need for ophthalmic ambulatory surgical services, nor the ability to provide quality of services. Again, no other ASC review criteria contains an arbitrary requirement that the applicant invest in a minimum dollar amount of healthcare technology. Furthermore, the $300,000 threshold unnecessarily restricts access to ophthalmic surgery procedures that do not require the use of laser technology. Most ophthalmology practices do not utilize laser technology for ophthalmic surgical procedures in ASCs. When advanced laser technology is utilized, it is generally in the context of cataract surgical cases where a femtosecond laser may be used. However, the use of such a laser has not been deemed medically necessary by Medicare and other payors and therefore, is not a covered benefit. Accordingly, because advanced laser technology is not necessary to perform ophthalmic surgeries in an ASC, an applicant should not be required to invest in such technology in order to establish an ASC.

Thank you again for the opportunity to submit the foregoing comments regarding the proposed revisions to 900 KAR 5:020 and the *2020-2022 State Health Plan* review criteria for ambulatory surgical centers."

(b) Response: The Cabinet appreciates the comments from Randy Strause, Strause Law Group, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Janet A. Craig, Stites and Harbison PLLC, on behalf of Pikeville Medical Center, provided the following comments:

"I am writing to you as counsel on behalf of Pikeville Medical Center, Inc. ('PMC') regarding 900 KAR 5:020's proposed revisions to the State Health Plan ('SHP'). Specifically, PMC opposes the changes in ambulatory surgery center ('ASC') criteria, which create a broad exemption from application of the current utilization criteria in the SHP for certain hospitals seeking to establish an ASC. PMC believes that the proposed changes in the State Health Plan related to ambulatory surgery centers will greatly impact PMC's ability to continue to provide the critical specialty care that PMC currently provides to residents of Eastern Kentucky. PMC also encourages the Cabinet to remove criteria for Ambulances from the SHP to improve timely access to emergency medical services.

Background on PMC

PMC is a not-for-profit hospital located in Pikeville, Pike County, Kentucky with 348 licensed acute care beds and 20 physical rehabilitation beds. Pike County is Kentucky's largest by land area, comprising 789 square miles and with a population of approximately 60,000 residents. PMC provides care to a broader region in Eastern Kentucky and neighboring states.

PMC serves as a regional referral center and provides complex specialty services that other hospitals in the area cannot provide. These services include open heart surgery, a structural heart program providing the latest available interventions, neurosurgery, a

Level II advanced care neonatal intensive care unit, interventional radiology, hyperbaric oxygen therapy, intensive care services fully staffed by physicians trained in critical care medicine, complex cancer treatment and clinical trials in our Leonard Lawson Cancer Center, unparalleled orthopedic surgery, and others. PMC is the state's only accredited Level II trauma center (the University of Kentucky and University of Louisville are the state's only Level I trauma centers). PMC has physicians available to provide care in every major adult specialty and many subspecialties. In most specialties PMC has multiple providers and round the clock on call coverage. PMC has recently established the Appalachian Valley Autism Center to begin addressing the needs of autistic children in the region to provide key services that were previously unavailable. PMC also maintains advanced technology throughout its facility. PMC's medical equipment rivals or exceeds most academic medical centers. PMC is also in the process of creating the first children's hospital in its region.

Many of these services would not be available in Eastern Kentucky if PMC did not provide them which means that patients would be forced to endure the burden of traveling several hours outside the region to find comparable care. PMC's past experience demonstrates that not all patients will make that journey. Therefore, PMC represents an important healthcare access point in Eastern Kentucky, particularly for complex specialty services. While many of PMC's services are vitally important for the health and wellbeing of its community, many are marginal revenue producers. Like most hospitals, PMC depends on revenue from outpatient surgery.

In addition to providing local access to key primary and specialty medical services, PMC is also a major employer and economic driver for Eastern Kentucky. PMC currently employs approximately 2,900 employees (down from over 3,000 prior to the COVID-19 pandemic) living in 32 Kentucky counties. PMC represents 25% of Pike County's total salaries and 49.8% of Pikeville's occupational tax. PMC offers good-paying jobs with great employee benefits in a region that has seen devastating coal job losses. If PMC's service offerings were curtailed, it would mean job loss in the region. When patients travel outside the area to receive care, it represents healthcare spending leaving the local economy and, in some cases, the state's economy. PMC also provides millions of dollars of charity care each year and has done so throughout its history.

PMC has invested heavily in healthcare infrastructure to serve the needs of the community both in terms of physical facilities (1.7 million square feet of space in 43 different buildings) and advanced technology including, but not limited to an ongoing $32 million heart institute renovation and expansion. Many of PMC's projects are financed with significant amounts of debt from the USDA and others. Although PMC has received some federal stimulus payments, like other hospitals, COVID-19 has had a dramatic negative effect on PMC's patient volumes and, therefore, its finances.

PMC also maintains robust partnerships with many educational institutions. PMC provides telehealth through the region, but is also implementing a specific telehealth program with the Pikeville and Pike County school districts. In addition to serving as a clinical education site for many colleges and universities in multiple disciplines, PMC has

partnered with Big Sandy Community and Technical College and the University of Pikeville to expand their nursing programs to combat the state-wide nursing shortage. PMC also works with the University of Pikeville's Kentucky College of Osteopathic Medicine and Kentucky College of Optometry, both as a training facility for students and a faculty practice site. In addition, certain members of PMC's medical staff serve as adjunct faculty at the medical school and PMC maintains its own accredited physician residency program.

Ambulatory Surgery Centers

The Kentucky State Health Plan (SHP) contains criteria that must be satisfied in order to obtain a Certificate of Need (CON) to establish or expand certain new health facilities or services. An ambulatory surgery center (ASC) is one of the types of facilities that requires a CON and is covered by the SHP. The SHP has for a long time contained a specific formula that must be met, except in very limited circumstances, before a CON is granted to establish a new ASC. The formula takes into account the number of surgeries performed and the number of existing hospital and ASC operating rooms in the area and is designed to ensure that the existing operating rooms are being sufficiently utilized before a new ASC is permitted.

The Cabinet for Health and Family Services issued a regulation (900 KAR 5:020) on April 7, 2020 containing amendments to the SHP affecting establishment of ASCs by hospitals. These amendments make it easier for certain hospitals to establish ASCs. The amendment exempts hospitals from almost all of the usual SHP criteria required to obtain a CON to establish an ASC (including the utilization formula described above) if the proposed new ASC:

- Is majority-owned by the hospital;
- Is in the same county as the hospital;
- Is in a county that has a population over 30,000; and
- The hospital has achieved a sufficient 'star rating' on the Hospital Compare website.

PMC opposes this proposed revision to the ASC criteria in the SHP for multiple reasons. First, it would allow a competitor hospital located in the same county to place an ASC in the same community and, indeed, essentially right on the doorstep of another hospital. As described earlier, Pike County is large geographically. Like many other rural counties, it is made up by several small communities separated by countryside in between, rather than a single unified community as is seen in urban counties. There is another hospital located in a separate community more than 28 miles from PMC, but still within Pike County. The proposed SHP change could enable that hospital (if they can achieve the required star rating) to place an ASC in Pikeville and drain away valuable outpatient surgery revenue from its facility. PMC desperately needs that revenue in order to continue to make key specialty services available to the region and maintain current levels of charity care. PMC could not make up that lost revenue by raising its prices. The vast majority of its patients have Medicare or Medicaid where the reimbursement is fixed. PMC also could not make up all of the lost revenue by placing its own ASC in the other

hospital's community in Pike County because it is a smaller community with naturally lower patient demand. PMC could not make up the lost revenue by placing an ASC in a more attractive location in a neighboring county because the proposal requires the ASC to be in the same county as its hospital owner. Without the ability to make up for the lost revenue, the only other option is to reduce costs by curtailing services. That means lack of access for patients to the detriment of their wellbeing and economic loss for the community.

While I have described PMC's specific circumstance above, there are broader considerations at stake. PMC would not be the only rural hospital negatively impacted in this way by the proposed change to the ASC SHP criteria. Rural healthcare is a difficult business financially. There have been several rural hospital closures nationally in the last few years. Hospitals have demonstrated their importance as critical pieces of infrastructure during the COVID-19 pandemic, but the pandemic has also strained hospitals' financial underpinning and demonstrated the importance of elective surgery revenue to their viability. While the proposed SHP changes may have been conceived prior to the pandemic, the current state of hospitals must be taken into account when making the final decision on whether or not to make the proposed changes final. No action should be taken which exacerbates the financial hardship that the pandemic has placed on hospitals.

Next, the stated purpose of CON is to prevent proliferation of unnecessary health facility that results in costly duplication and underuse (KRS 216B.010). Establishing new ASCs without regard to the utilization formula in the current SHP goes against that stated purpose. If the existing operating rooms in the area of the new ASC are not being sufficiently utilized already, then adding more operating rooms creates duplication and further underutilization. Further, as explained above, while additional ASCs may increase the supply of operating rooms in counties that qualify under the new proposed criteria, it will actually cause an overall decrease in access to a broader range of other healthcare services by draining outpatient surgery revenue from hospitals that they need in order to be able to continue to provide other services.

The proposed SHP changes are also unnecessary to accomplish the usual goals of ASCs. If certain hospitals desire to establish an ASC due to pressure from commercial third party payers, the issue can be addressed through payer price negotiation and contracting without disturbing the SHP at all. Further, ASC proponents typically argue that it is a win-win proposition by citing lower prices for patients and their insurer and simultaneously lower costs for the provider. The lower provider costs can be true in terms of cost of the space to house the ASC as compared to the cost of building hospital operating rooms, but is not actually true in terms of the cost of personnel and equipment and their argument ignores the possibility that operating rooms which already exist in the area (whether in hospitals or ASCs) may already be underutilized which points to the need to retain the SHP utilization formula.

Even if those considerations are ignored and the preference is to enable hospitals to establish new ASCs, it is blatantly unnecessary to permit them to place the new ASC

anywhere in the hospital's home county. If there are legitimate cost-related goals to be achieved with additional hospital-owned ASCs, those goals can still be attained by requiring the hospital to place the new ASC on or adjacent to its existing campus. This would prevent a hospital in one community from placing their new ASC on the doorstep of another hospital in a separate community within the same county and ensure that any increase in operating room underutilization caused by the new ASC would only occur at the hospital which establishes the new ASC. Indeed, cost reductions goals would actually be furthered by locating the ASC on or adjacent to the owning hospital's campus due to the increased efficiency of the hospital and ASC being able to easily share surgical staff.

The effect of the proposed ASC criteria change on the CON system as a whole should also be considered. Kentucky's CON system is the subject of ongoing legal challenges and there have been legislative attempts in the recent past to curtail or eliminate it. Creating another special exception for the specific benefit of a few hospitals while continuing to exclude others from establishing a new ASC unless they can meet the current utilization formula will provide additional ammunition to anti-CON proponents in their quest to end CON. Further, the fact that the proposal indeed appears designed to benefit a few specific hospitals raises the possibility that it is unconstitutional special regulation. Even if that is not the case, the appearance of it invites litigation which will be expensive for the state and for providers. That money could be better spent providing healthcare to the citizens of the Commonwealth.

The proposed ASC criteria changes weaken Kentucky's CON system as a whole, will cause financial detriment to hospitals that lead to curtailment of vital services to the community, will weaken the local economy, and are unnecessary to accomplish legitimate goals. Even if those arguments are ignored, the worst time to make the proposed changes would be in the middle of a pandemic emergency and its attendant economic slowdown. If the Cabinet nevertheless feels that the ASC criteria must be amended, then the proposed changes should be modified to require the hospital-owner of the new ASC to locate it on or adjacent to the hospital's existing campus so that the decreased operating room utilization, and the related financial damage, is restricted to that hospital and causes less damages to other hospitals."

(b) Response: The Cabinet appreciates the comments from Janet A. Craig, Stites and Harbison PLLC, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Hollie H. Phillips, Vice President, Corporate Strategy, Appalachian Regional Healthcare, provided the following comments:

"We support revisions on page 54, criterion 7, conditions 'a-d' and 'f' that would enable a Kentucky-licensed acute care hospital, accredited by an organization approved by the Centers for Medicare and Medicaid Services (CMS), to establish an ambulatory surgical center (ASC) in the county in which it is located to improve access to quality care and

reduce costs. It is critical that hospitals have this option while the federal government is redirecting and reducing its spending on health care services. The U.S. Department for Health and Human Services is transitioning to a value-based payment model, pressuring providers and payers to develop lower cost strategies for health care delivery. Hospitals are responding by entering into value-based arrangements with physicians, employers and payers. Another proven strategy is to provide surgeries in lower cost settings, such as ASCs.

When considering both fixed and variable costs, it is more costly to provide care in a hospital than in a free standing ASC. It makes sense, therefore, for an acute care hospital to establish an ASC for patients within its own network. Shifting care to an ASC maximizes operational efficiency due to a more narrowly defined scope of work. Staffing and supplies are managed more efficiently due to the predictability of services provided, thereby reducing costs. Payers currently are steering patients to ASCs, so it is important that these facilities be available to our patients.

Our health system has a long history of providing safe and quality care and is fully committed to continuous quality improvement. ARH is accredited by the DNV, which is part of our license renewal process and is required for reimbursement for federally-funded programs, assures the public that hospitals meet federal industry standards in quality and patient safety. Meeting or exceeding these predetermined standards ensures greater consistency in care, better safety processes are in place, and overall a higher quality of care.

As currently written, condition 'f' in criterion 7 assures that quality and safety standards have been met in the applicant hospital through its accreditation. We recommend that the following language be added to condition 'f' to ensure the ASC earns accreditation. With this change, we believe that the intended goal of condition 'e' in criterion 7 has been met.

> f. The applicant hospital shall be accredited by an accrediting organization approved by the Centers for Medicare and Medicaid Services, including the Joint Commission or another nationally recognized accrediting organization with comparable standards and survey processes. <u>The separately licensed ASC facility, which shall provide services to Medicare and Medicaid beneficiaries, shall earn accreditation through the Accreditation Association for Ambulatory Health Care, Joint Commission, or other accreditation program approved by the federal government.</u>

Condition 'e' requires that the applicant hospital's overall rating by the CMS Hospital Compare was four stars or higher for three out of the last four reported quarters preceding the date the application was filed. We recommend that 'e' be deleted in the final State Health Plan based on the following reasons:

1) Quality assurances are met in condition 'f' with recommended changes.

2) Hospital Compare provides information for comparing hospitals across the country based on an overall star rating. Unfortunately, the ratings are not properly adjusted for social determinants of health, which the Centers for Disease Control and Prevention (CDC) define as 'the conditions in which people are born, grow,

live, work and age, as well as the complex, interrelated social structures and economic systems that shape these conditions. Social determinants of health include aspects of the social environment (e.g., discrimination, income, education level, marital status), the physical environment (e.g., places of residence, crowding conditions, built environment), and health services (e.g., access to and quality of care, insurance status.)' The CDC also recognizes that 'poverty limits access to healthy foods and safe neighborhoods and that more education is a predictor of better health.'

Hospitals located in poverty stricken areas of Kentucky, such as Appalachia, cannot be compared fairly to hospitals in more affluent urban areas. Likewise, since Kentucky is such a poor state, ranking 4th in poverty rate, its hospitals should not be compared to those in other states until the CMS Hospital Compare's methodology is revised to adjust for social determinants of health.

3) Hospital Compare ratings are based on patients' subjective assessment of their hospital experience and not on clinical outcomes. The medical community has challenged CMS on the credibility and reliability of the star rating program. Until this long-standing controversy is clarified, we recommend that the stated Hospital Compare ratings not be a condition that must be met in the Kentucky State Health Plan.

Revised language on page 52 clarifies that the normal driving time from location of a new ASC to an acute care hospital be thirty (30) minutes, and that a transfer agreement be in place between a new ASC and an acute care hospital that is located within thirty (30) minutes normal driving time of the center. We are supportive of these revisions."

(b) Response: The Cabinet appreciates the comments from Hollie H. Phillips, Appalachian Regional Healthcare, regarding the proposed amendment of the State Health Plan 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Jody Prather, M.D., Chief Strategy and Marketing Officer, Baptist Health, provided the following comments:

"Before addressing specific changes to the SHP, Baptist would like to comment on the impact of COVID-19 on Kentucky providers as it relates to the SHP. Kentucky's healthcare providers have effectively managed the COVID-19 outbreak, but it has come at a great cost. Providers have experienced a steep decline in revenue resulting from the cancellation of elective procedures and office visits. Elective procedures have resumed, but volumes remain down significantly and are not expected to return to normal before the end of 2020. Under these circumstances, Baptist does not believe it is prudent to make changes to the SHP. Revision of SHP criteria could inflict additional financial harm on healthcare providers when they are already financially vulnerable.

Baptist is concerned that the proposal to add a new Criterion No. 7 to the criteria for an ambulatory surgical center ('ASC') could result in the proliferation of ASCs in Kentucky at a time when the state already has a glut of operating room capacity. Every Area Development District ('ADD') in Kentucky has significant excess operating room capacity. The SHP sets the target utilization for operating rooms at 85%, but the Ambulatory Surgical and Hospital Utilization Reports for 2018 show that no ADD had more than 55.7% operating room utilization. Every ADD had excess operating rooms ranging from three to 89. Graphs showing Kentucky's excess surgical capacity are being submitted with these comments. Furthermore, the downturn in procedures that hospitals and ASCs have experienced as a result of COVID-19 has only exacerbated the excess capacity problem in Kentucky."

(b) Response: The Cabinet appreciates the comments from Jody Prather, M.D., Baptist Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Sherri Craig, Market Vice President, Public Policy, CHI Saint Joseph Health, provided the following comments:

"We support revisions on page 54, criterion 7, conditions 'a-d' and 'f' that would enable a Kentucky-licensed acute care hospital, accredited by an organization approved by the Centers for Medicare and Medicaid Services (CMS), to establish an ambulatory surgical center (ASC) in the county in which it is located to improve access to quality care and reduce costs. It is critical that hospitals have this option while the federal government is redirecting and reducing its spending on health care services. The U.S. Department for Health and Human Services is transitioning to a value-based payment model, pressuring providers and payers to develop lower cost strategies for health care delivery. Hospitals are responding by entering into value-based arrangements with physicians, employers and payers. Another proven strategy is to provide surgeries in lower cost settings, such as ASCs.

When considering both fixed and variable costs, it is more costly to provide care in a hospital than in a free standing ASC. It makes sense, therefore, for an acute care hospital to establish an ASC for patients within its own network. Shifting care to an ASC maximizes operational efficiency due to a more narrowly defined scope of work. Staffing and supplies are managed more efficiently due to the predictability of services provided, thereby reducing costs. Payers currently are steering patients to ASCs, so it is important that these facilities be available to our patients.

Our health system has a long history of providing safe and quality care and is fully committed to continuous quality improvement. Accreditation by the Joint Commission, which is part of our license renewal process and is required for reimbursement for federally-funded programs, assures the public that hospitals meet federal industry standards in quality and patient safety. Meeting or exceeding these predetermined

standards ensures greater consistency in care, better safety processes are in place, and overall a higher quality of care.

As currently written, condition 'f' in criterion 7 assures that quality and safety standards have been met in the applicant hospital through its accreditation. We recommend that the following language be added to condition 'f' to ensure the ASC earns accreditation. With this change, we believe that the intended goal of condition 'e' in criterion 7 has been met.

> 'f' The applicant hospital shall be accredited by an accrediting organization approved by the Centers for Medicare and Medicaid Services, including the Joint Commission or another nationally recognized accrediting organization with comparable standards and survey processes. The separately licensed ASC facility, which shall provide services to Medicare and Medicaid beneficiaries, shall earn accreditation through the Accreditation Association for Ambulatory Health Care, Joint Commission, or other accreditation program approved by the federal government.

Condition 'e' requires that the applicant hospital's overall rating by the CMS Hospital Compare was four stars or higher for three out of the last four reported quarters preceding the date the application was filed. We recommend that 'e' be deleted in the final State Health Plan based on the following reasons:

1) Quality assurances are met in condition 'f' with recommended changes.

2) Hospital Compare provides information for comparing hospitals across the country based on an overall star rating. Unfortunately, the ratings are not properly adjusted for social determinants of health, which the Centers for Disease Control and Prevention (CDC) define as 'the conditions in which people are born, grow, live, work and age, as well as the complex, interrelated social structures and economic systems that shape these conditions. Social determinants of health include aspects of the social environment (e.g., discrimination, income, education level, marital status), the physical environment (e.g., places of residence, crowding conditions, built environment), and health services (e.g., access to and quality of care, insurance status.)' The CDC also recognizes that 'poverty limits access to healthy foods and safe neighborhoods and that more education is a predictor of better health.' Hospitals located in poverty stricken areas of Kentucky, such as inner cities or Appalachia, cannot be compared fairly to hospitals in more affluent areas. Likewise, since Kentucky is such a poor state, ranking 47th in poverty rate, its hospitals should not be compared to those in other states until the CMS Hospital Compare's methodology is revised to adjust for social determinants of health.

3) Hospital Compare ratings are based on patients' subjective assessment of their hospital experience and not on clinical outcomes. The medical community has challenged CMS on the credibility and reliability of the star rating program. Until this long-standing controversy is clarified, we recommend that the stated Hospital Compare ratings not be a condition that must be met in the Kentucky State Health

Plan.

Revised language on page 52 clarifies that the normal driving time from location of a new ASC to an acute care hospital be thirty (30) minutes, and that a transfer agreement be in place between a new ASC and an acute care hospital that is located within thirty (30) minutes normal driving time of the center. We are supportive of these revisions."

(b) Response: The Cabinet appreciates the comments from Sherri Craig, Market Vice President, Public Policy, CHI Saint Joseph Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Jeff R. Ellison, Chief Operating Officer, Commonwealth Pain and Spine, provided the following comments:

"Commonwealth Pain Associates, PLLC d/b/a Commonwealth Pain and Spine ('Commonwealth') proposes important changes to the State Health Plan's Review Criteria for Ambulatory Surgery Centers necessary to create an opportunity for Physician Owned Pain Management Clinics, registered with the Kentucky Board of Medical Licensure, to establish ambulatory surgery centers for interventional pain procedures. As a result of the opioid epidemic and Kentucky's regulation of physicians and other practitioners' treatment of chronic pain patients, the operation of pain treatment centers is highly regulated and limited. The Kentucky Board of Medical Licensure regulates the operation of Physician Owned Pain Management Clinics through a registration and review process and has enforcement authority through its disciplinary process. As the pain management specialty has evolved and become more sophisticated and complex, so have the technology, medical devices and procedures that physicians practicing in this area use. As new and more sophisticated procedures and interventions develop, pain management physicians are developing an arsenal of tools including surgical procedures to address the medical needs of chronic pain patients, which, in turn, reduces the need to manage patients with long term opioid treatment. Thus, there is a need to change the State Health Plan Review Criteria for ASCs to provide an opportunity for Physician Owned Pain Management Clinics to secure a certificate of need and establish specialty ASC's for the benefit of interventional pain patients.

Interestingly, the State Health Plan's Review Criteria for ASCs already favors creating an exception for ASCs that provide interventional pain procedures. The current definition of outpatient surgical utilization and the complex formula for determining threshold utilization for establishment of new ASCs already excludes pain procedures performed even when reported as surgical procedures in the Kentucky Annual Ambulatory Surgical Services Report and The Kentucky Annual Ambulatory Hospital Utilization and Services Report. The State Health Plan Review Criteria simply does not define 'pain procedures' as surgical procedures in the first place.

Amending the State Health Plan to provide opportunities for Physician Owned Pain Management Clinics to secure a certificate of need to establish an ASC is supported by several very important factors. First, creating an exception for ASCs that provide interventional pain procedures and surgeries will improve access to important and medically necessary treatments, particularly in rural areas. Second, if approved, an ASC providing interventional procedures and surgeries has the ability to reduce consumer costs by shifting the site of care from expensive outpatient hospital departments to less expensive ASCs. Third, providing interventional procedures and surgeries in an ASC that is accredited, certified and licensed, will increase the opportunity to provide safer and higher quality interventional pain procedures and services deemed necessary to serve chronic pain patients. Chronic pain practices serve a higher majority of medically complex patients (such as morbidly obese patients, patients with multiple chronic conditions and the elderly) due to the nature of chronic pain. While some interventional procedures may be provided in physicians' offices, the level of complexity of the procedure and condition of the patient often mandate that the procedure be provided in a surgical suite in a manner consistent with ASC standards or in a hospital outpatient surgery department at a higher cost. Fourth, limiting the exception to physicians that have registered as Physician Owned Pain Management Clinics also assures that the quality of care will be overseen and provided by a medical director that is board certified with experience in the pain specialty. And, of course, the Kentucky Board of Medical Licensure has the ultimate enforcement authority to assure that services are provided in a manner consistent with accepted standards of care. Fifth, the exception will create opportunities for Physician Owned Pain Management Practices to expand interventional services to rural areas where there are no ASCs and improve access to care. For example, our physicians practicing in rural areas are limited in the services that they are able to provide to their rural patients in a convenient and cost-effective manner. With the prevalence of chronic pain patients and substance disorder patients, there is a crucial need to expand access to interventional pain procedures.

We propose that the review criterion be changed as follows:

> Notwithstanding criteria 1, 3, and 4, an application to establish an ASC limited to intervention pain surgery procedures shall be consistent with this Plan if the following conditions are met:
>
> 1. The Applicant is an entity owned solely by physicians licensed to practice medicine in the Commonwealth of Kentucky;
>
> 2. The Applicant is registered as a Physician-Owned Pain Management Facility with the Kentucky Board of Medical Licensure and is operated in a manner consistent with KRS 218A.175 and 201 KAR 9:250;
>
> 3. The Applicant documents that interventional pain procedures have been performed by the physician owners for Kentucky patients for a period of five (5) years prior to the date the application was submitted; and

4. The proposed ASC is located in a county, which is a registered practice location of the Physician-Owned Pain Management Facility.

Commonwealth requests that the review criteria for ambulatory surgery centers be changed to allow approval of applications proposing to establish ambulatory surgery centers which provide interventional pain treatment for patients."

(b) Response: The Cabinet appreciates the comments from Jeff R. Ellison, Chief Operating Officer, Commonwealth Pain and Spine, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Janet A. Craig, Attorney, Stites and Harbison PLLC, provided the following comments:

"Please accept these comments as counsel on behalf of Endoscopy and Surgical Center of Lexington Clinic and the Lexington Clinic Surgery Center ('ASCs') regarding the proposed change in 900 KAR 5:020 to the ambulatory surgery criteria in the proposed 2020-2022 Kentucky State Health Plan ('SHP'). The ASCs are freestanding licensed ambulatory surgery centers located in Lexington, Kentucky just minutes from CHI Saint Joseph Hospital's campus. The ASCs oppose the proposed changes to the ambulatory surgery center ('ASC') criteria, which creates a broad exemption for ASCs majority owned by a hospital from the application of the utilization criteria currently in the SHP.

The ASCs believe the proposed change creates an exception that does not take into account the current utilization and existing capacity for outpatient surgery services and, therefore, would harm existing facilities, could result in increased costs to the health care delivery system and proliferation of health care facilities in contravention to the statutory mandate of KRS Chapter 216B. Moreover, the proposed exemption is unfair in that it only provides an exception for ASCs majority owned by hospitals, not for other free standing surgery health care providers. The timing of this amendment occurring after existing ASCs were virtually shut down for months in compliance with the Governor's Executive Order during the Covid-19 pandemic also exacerbates the financial strain on existing ASCs and hospitals which had to forego elective surgeries, many of which would have been performed in an outpatient setting.

KRS 216B.040 authorizes and mandates the creation of The Kentucky State Health Plan as the state health planning document. KRS Chapter 216B.010 states clearly that the purpose of the certificate of need law is to carry out the Legislative intent 'that the proliferation of unnecessary health-care facilities, health services and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the

Commonwealth.' Ambulatory surgery centers are health facilities subject to Certificate of Need law and regulations. Consistent with the statutory charge of KRS 216B.010, the SHP has historically contained a specific formula that must be met, except in very limited circumstances, before a CON is granted to establish a new ASC. The formula takes into account the number of surgeries performed in the proposed service area and the number of existing hospital and ASC operating rooms in the area which are available to meet the expected needs for such services. This formula, consistent with CON law, is designed to ensure that the existing operating rooms, both in freestanding ASCs and hospital settings, are being sufficiently utilized before a new ASC with additional operating rooms is permitted.

900 KAR 5:020, published by the Cabinet on April 7, 2020, contains amendments to the ASC criteria in the SHP which creates an exemption to satisfying this utilization formula by certain applicants. If adopted, this new ASC criteria would create an exception that allow a select few providers to establish ambulatory surgery centers without meeting any SHP utilization requirements. The amendment exempts these applicants from almost all of the usual SHP criteria required to obtain a CON to establish an ASC (including the utilization formula described above) if the proposed new ASC:

- Is majority-owned by the hospital;
- Is in the same county as the hospital;
- Is in a county that has a population over 30,000; and
- The hospital has achieved a sufficient 'star rating' on the Hospital Compare website.

As noted above, the stated purpose of CON is to prevent proliferation of unnecessary health care services that results in costly duplication and underuse. (KRS 216B.010.) Establishing new ASCs without regard to the utilization formula in the current SHP goes against that stated purpose. If the existing operating rooms in the area of the new ASC are not being sufficiently utilized already, then adding more operating rooms creates duplication and further underutilization. Further, while additional ASCs may increase the supply of operating rooms in counties that qualify under the new proposed criteria, it will actually cause an overall decrease in access to a broader range of other healthcare services by draining outpatient surgery revenue from providers that rely on this revenue to provide other services. This would lead to the weakening of providers that are already financially strained by the effects of nearly full closure due to Covid-19. Adding ASCs where there is no need and putting a further financial strain on existing providers including ASCs that depend on revenue from their operating rooms is contrary to the good health planning, especially in a post Covid-19 world.

There is no scarcity of operating rooms in counties with population of over 30,000. For example, in Fayette County, a county with a population of over 30,000, which would be affected by this exemption, has an abundance of outpatient operating rooms. This capacity includes four hospitals, and 17 licensed ambulatory surgery centers. According to the 2019 Annual Ambulatory Surgical Services Report, there are 134 inpatient and outpatient operating rooms in the county and 59 ambulatory only operating rooms. Since

existing hospitals and ambulatory surgery centers can add additional operating rooms without obtaining a certificate of need, there is a built in mechanism to meet additional need if it were to exist at a later date. Accordingly, it cannot be argued that there is any need for another ASC in Fayette County. Fayette County is not alone in this respect. Other large population areas in the Commonwealth, such as Jefferson County and the counties in Northern Kentucky, have plenty of OR capacity. Proponents of this change do not need an ambulatory surgery center, they simply 'want' their own freestanding facilities. There clearly is no need for additional ambulatory surgery centers in an area where utilization and capacity requirements are not met as required by the current SHP.

For all of the above reasons, the ASCs encourage this proposed change to the SHP criteria for ambulatory surgery centers be deleted. Thank you for consideration of these comments."

(b) Response: The Cabinet appreciates the comments from Janet Craig, Attorney, Stites and Harbison PLLC, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comments: Wade R. Stone, Executive Vice President of Med Center Health, provided the following comments:

"On behalf of Med Center Health, I am submitting these written comments on the proposed 2020-2022 State Health Plan, 900 KAR 5:020.

Ambulatory Surgical Centers - Star Rating Criterion - Med Center Health would like to comment specifically on the proposed changes to the SHP criteria for an ambulatory surgical center ('ASC'). On page 54 of the proposed SHP, the Cabinet has added a new Criterion No. 7 covering an application submitted by a Kentucky-licensed acute care hospital proposing to establish an ASC in the same county. One of the added criteria states that the 'applicant hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was four (4) stars or higher for three (3) out of the last four (4) reported quarters preceding the date the application was filed.' Med Center Health understands the desire to add criteria addressing quality to the SHP, but the Hospital Compare Star Rating system is widely viewed as inaccurate. Including this criterion will not improve the quality of ASCs established in the Commonwealth.

Researchers from Rush University Medical Center have shown that the Hospital Compare Star Rating system is deeply flawed. They have proven that CMS calculates star ratings in a way that disadvantages hospitals that treat highly acute patients. A hospital's location and patient mix are two of the biggest factors in its score because the star rating system does not take into account the socioeconomic status of hospitals' patients. CMS adjusts readmission scores so that large hospitals with high patient volumes are adversely affected. Finally, the statistical methods used by CMS causes inconsistencies in the

ratings. See https://www.rushu.rush.edu/news/rush-hospitals-receive-four-stars-rush-leaders-recommend-four-changes-ratings-system

The American Hospital Association ('AHA') has taken the position that the 'star ratings approach does not provide an accurate picture of hospital quality performance.' The AHA has shown that the ratings 'are driven by methodology rather than actual hospital performance.' A copy of the February 1, 2019 letter from AHA to CMS is enclosed with these comments. For these reasons, including the Hospital Compare Star Ratings in the proposed Criterion No. 7 for ASCs would be a mistake."

(b) Response: The Cabinet appreciates the comments from Wade R. Stone, Executive Vice President of Med Center Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Mary Jo Bean, Senior Vice President, Planning and Business Analysis, Norton Healthcare, Inc., provided the following comments:

"Thank you so much for the opportunity to comment on the proposed revisions to the State Health Plan. We appreciate the Cabinet's continued efforts to modernize the Kentucky State Health Plan. Overall, we are supportive of the proposed changes in the 2020-2022 State Health Plan. However, we do have some concerns relative to the modifications to the Ambulatory Surgery Center criteria, specifically the insertion of criteria #7 on page 54 of the draft document.

We support revisions on page 54, criterion 7, conditions 'a-d' and 'f' that would enable a Kentucky-licensed acute care hospital, accredited by an organization approved by the Centers for Medicare and Medicaid Services (CMS), to establish an ambulatory surgical center (ASC) in the county in which it is located to improve access to quality care and reduce costs. It is critical that hospitals have this option while the federal government is redirecting and reducing its spending on health care services. The U.S. Department for Health and Human Services is transitioning to a value-based payment model, pressuring providers and payers to develop lower cost strategies for health care delivery. Hospitals are responding by entering into value-based arrangements with physicians, employers and payers. Another proven strategy is to provide surgeries in lower cost settings, such as ASCs.

When considering both fixed and variable costs, it is more costly to provide care in a hospital than in a free standing ASC. It makes sense, therefore, for an acute care hospital to establish an ASC for patients within its own network. Shifting care to an ASC maximizes operational efficiency due to a more narrowly defined scope of work. Staffing and supplies are managed more efficiently due to the predictability of services provided, thereby reducing costs. Payers currently are steering patients to ASCs, so it is important that these facilities be available to our patients.

As you are aware, Norton Healthcare (Norton) operates five acute care hospitals in the Louisville, area, including Norton Children's Hospital as part of Norton Hospital/Norton Medical Pavilion. Norton also operates five (5) diagnostic centers, thirteen (13) immediate care centers, eight (8) retail clinics and more than 200 practice locations. We've expanded our post-acute care services to include ambulatory rehab and home health, via our joint venture partners. Norton currently operates one ambulatory surgery center but it is dedicated to pediatric ambulatory procedures. As such, while we have a strong integrated delivery system in the state, we lack the ability to offer our adult patients an ambulatory surgery option, so this could fill a big void in the care continuum for the Norton system.

Our health system has a long history of providing safe and quality care and is fully committed to continuous quality improvement. Accreditation by the Joint Commission, which is part of our license renewal process and is required for reimbursement for federally-funded programs, assures the public that hospitals meet federal industry standards in quality and patient safety. Meeting or exceeding these predetermined standards ensures greater consistency in care, better safety processes are in place, and overall a higher quality of care.

It is our understanding that condition 'e', which requires that the applicant hospital's overall rating by the CMS Hospital Compare was four stars or higher for three out of the last four reported quarters preceding the date the application was filed, was included to ensure a quality standard would be met by any new facility. Of course, historical ratings are not readily available on the CMS Hospital Compare website, but certainly an applicant could provide this information.

Nonetheless, we recommend that 'e' be deleted in the final State Health Plan based on the following reasons:

1. Quality assurances are met in condition 'f' with recommended changes, which are outlined below.

2. Hospital Compare provides information for comparing hospitals across the country based on an overall star rating. Unfortunately, the ratings are not properly adjusted for social determinants of health, which the Centers for Disease Control and Prevention (CDC) define as 'the conditions in which people are born, grow, live, work and age, as well as the complex, interrelated social structures and economic systems that shape these conditions. Social determinants of health include aspects of the social environment (e.g., discrimination, income, education level, marital status), the physical environment (e.g., places of residence, crowding conditions, built environment), and health services (e.g., access to and quality of care, insurance status.)' The CDC also recognizes that 'poverty limits access to healthy foods and safe neighborhoods and that more education is a predictor of better health.'

3. Hospitals located in poverty stricken areas of Kentucky, such as inner cities or

Appalachia, cannot be compared fairly to hospitals in more affluent areas. Likewise, since Kentucky is such a poor state, ranking 47th in poverty rate, its hospitals should not be compared to those in other states until the CMS Hospital Compare's methodology is revised to adjust for social determinants of health.

4. Hospital Compare ratings are based on patients' subjective assessment of their hospital experience and not on clinical outcomes. The medical community has challenged CMS on the credibility and reliability of the star rating program. Until this long-standing controversy is clarified, we recommend that the stated Hospital Compare ratings not be a condition that must be met in the Kentucky State Health Plan.

5. In Norton's case, as a result of our single provider number with CMS, all facilities are scored collectively. As such, while some of our hospitals may meet the criteria to obtain four (4) stars or better, we don't have that ability due to our structure. In turn, as all Norton facilities are scored collectively, our hospitals are not allowed fair and equitable treatment as compared to other Kentucky hospitals.

6. An alternative to Hospital Compare could be The Leapfrog Hospital Group, which provides a safety grade for hospitals in the spring and fall of each year. They utilize patient experience and infection data used by CMS in quality payment programs. They also have a safety survey that facilities have the option to submit. All Norton facilities received an 'A' grade for each of the last two periods and have received an A or a B for the last two years. Of course, the downside of using the Leapfrog Group is that they don't grade Critical Access Hospitals.

Condition 'f' in criterion 7 assures that quality and safety standards have been met in the applicant hospital through its accreditation. We recommend that the following language be added to condition 'f' to ensure the ASC earns accreditation. With this change, we believe that the intended goal of condition 'e' in criterion 7 has been met and further supports elimination of this criterion. We recommend modification of criterion 7.f. as follows:

f. The applicant hospital shall be accredited by an accrediting organization approved by the Centers for Medicare and Medicaid Services, including the Joint Commission or another nationally recognized accrediting organization with comparable standards and survey processes. <u>The separately licensed ASC facility, which shall provide services to Medicare and Medicaid beneficiaries, shall earn accreditation through the Accreditation Association for Ambulatory Health Care, Joint Commission, or other accreditation program approved by the federal government.</u>

This revision also ensures consistency with criterion 5. F, which reads as follows: 'The applicant documents that the proposed ASC shall be accredited within twelve (12) months of licensure by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/ Healthcare Facilities Accreditation

Program (AOA/HFAP), The Joint Commission (TJC), or another accreditation organization approved by the United States Centers for Medicare and Medicaid Services.'

Revised language on page 52 clarifies that the normal driving time from location of a new ASC to an acute care hospital be thirty (30) minutes, and that a transfer agreement be in place between a new ASC and an acute care hospital that is located within thirty (30) minutes normal driving time of the center. We are supportive of these changes."

(b) Response: The Cabinet appreciates the comments from Mary Jo Bean, EVP, CEO, Norton Healthcare, Inc., regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Anand Gupta, M.D., Paramount Surgery Center LLC, provided the following comments:

"Thank you for the opportunity to comment on the proposed revisions to 900 KAR 5:020 and the 2020-2022 State Health Plan ('SHP'). Please accept these comments on behalf of Paramount Surgery Center, LLC ('Paramount') and Dr. Anand M. Gupta. The Cabinet for Health and Family Services ('Cabinet') has revised the language in the SHP Ambulatory Surgical Center ('ASC') Review Criteria to enable a Kentucky-licensed acute care hospital to establish an ASC in the same county as the hospital. Paramount is proposing a similar addition that allows an existing and operating surgery center established under KRS 216B.020 limited to gastroenterology surgical procedures to establish an ASC.

Since 1998, Paramount has been providing individualized gastroenterology treatments and endoscopic procedures under KRS 216B.020, commonly referred to as the 'physician's office exemption,' in Louisville, Jefferson County, Kentucky. As one of the most established gastroenterology centers in Louisville, Paramount is a state-of-the-art facility with the latest technology that provides care and services in a relaxed and secure environment. One of Paramount's members and sole practitioner, Anand M. Gupta, M.D., is licensed in Kentucky and Indiana and certified by the American Board of Internal Medicine in the specialties of internal medicine and gastroenterology. Dr. Gupta is also a Fellow of the American College of Gastroenterology.

Paramount and Dr. Gupta support Kentucky's Certificate of Need ('CON') Program as it ensures the orderly growth and development of health care services. Paramount and Dr. Gupta also advocate for the ability of an existing, operational surgery center established under KRS 216B.020 to establish an ASC to increase access to outpatient gastroenterology surgical services. Along those lines, Paramount and Dr. Gupta propose that the following Review Criterion be added to the ASC Review Criteria:

9. Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application to establish an ASC limited to gastroenterology surgery procedures shall be consistent with this Plan if the following conditions are met:

a. The applicant is a gastroenterologist or gastroenterology group, 100% owned by physicians, which has been organized and practicing in Kentucky for a period of ten (10) years prior to the date the application was submitted;

b. The applicant documents that the proposed gastroenterology outpatient surgery procedures have been performed for a period of five (5) years prior to the date the application was submitted;

c. The proposed ASC is located in the county where the private office is currently located;

d. Only one (1) ASC shall be established by the applicant; and

e. The applicant documents that the proposed ASC is or shall be accredited within twelve (12) months of licensure by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), The Joint Commission (TJC), or another accreditation organization approved by the United States Centers for Medicare and Medicaid Services.

Inclusion of this new Review Criterion will meet the need for, and increase access to, gastroenterology surgical procedures, most importantly colonoscopies and upper endoscopies. Currently, almost all available time slots to perform endoscopies at hospital outpatient departments are used by employed physicians. This results in considerable unreasonable waiting times for patients of non-employed physicians needing routine endoscopy procedures. Further, an ASC specializing in gastroenterology endoscopies offers a substantially more cost-effective alternative to hospital outpatient departments, which cost more than 100 percent.

Over the last decade, the need for screening colonoscopy procedures has considerably increased; however, hospitals have not been able to accommodate those needs without incurring significant expenses. A large portion of Paramount's procedures involve colonoscopies that are used in the early detection of colorectal cancer. According to the American Cancer Society, in the United States, colorectal cancer is the third leading cause of cancer-related deaths in men and women, and the second most common cause of cancer deaths when men and women are combined. This cancer is expected to cause approximately 53,200 deaths during 2020.

The American Cancer Society estimates that, in 2020, there will be 104,610 new cases of colon cancer and 43,340 new cases of rectal cancer. Nationally, the death rate (the number of deaths per 100,000 people per year) from colorectal cancer has been dropping in both men and women for several decades. There are a number of likely reasons, but

the most significant one is that colorectal polyps are now being found more often by screening and removed before they can develop into cancers or are being found earlier when the disease is easier to treat. In addition, treatment for colorectal cancer has improved over the last few decades. As a result, there are now more than 1 million survivors of colorectal cancer in the United States. Although the overall death rate has continued to drop, deaths from colorectal cancer among people younger than age 55 have increased 2% per year from 2007 and 2016.

Despite these national statistics, colorectal cancer is a significant public health problem in Kentucky, and the second most commonly diagnosed invasive cancer affecting both men and women after lung cancer. Over 2,700 individuals are diagnosed with colorectal cancer in Kentucky each year. A greater burden is found among men, African-Americans, the Appalachian population, and rural areas. Kentucky continues to have the highest colorectal cancer incidence rate in the U.S. compared to all other states, due in part to low rates of preventative screenings. Based on data from the Centers for Disease Control for the period 2012 to 2016, Kentucky's rate of new colorectal cancer cases per 100,000 was 49.2, which was 27 percent higher than the United States average. Kentucky also has the sixth highest rate of deaths from colorectal cancer, with 16.8 deaths per 100,000 population compared to 13.7 deaths per 100,000 for the United States.

One troubling trend is the increasing rate of colorectal cancer incidence and mortality among individuals under age 55. Colon cancer is the second leading cause of death from cancers that affect both men and women, with 43 percent of young onset patients diagnosed between the ages of 45-49. The American Cancer Society responded to the increasing rates of early age onset colon cancer by lowering the age of initial colon cancer screening for normal risk individuals from 50 to 45. Colorectal screening is an important factor in decreasing mortality, and colonoscopies are the most effective tool for early diagnosis. This is why Kentuckians must have prompt access to screening colonoscopies.

Inclusion of this new SHP Review Criterion will allow an existing, operational surgical center providing gastroenterology procedures to focus on fulfilling patient's endoscopy and colonoscopy needs in an effective and cost-efficient manner, particularly when compared to the expense associated with providing the same procedures in a hospital outpatient department. Moreover, the current pandemic has created a very overburdened health care system which cannot reasonably accommodate routine, legitimately needed outpatient endoscopy and colonoscopy procedures. As detailed above, time is of the essence in identifying and treating gastroenterology diseases and cancers.

Moreover, inclusion of this new SHP Review Criterion will increase access to gastroenterology surgical procedures for patients insured by certain third party payors. Currently, some third party payors require a provider to be licensed as an ASC before it will credential the provider, as well as authorize and reimburse a provider, for the provision of gastroenterology surgical procedures. If the patient's provider is not a licensed ASC, and thus not credentialed with its insurer, the patient is forced to choose between foregoing the required procedure or having it performed at a different, more costly health care setting, possibly by another physician. As noted above, there are already delays is

accessing gastroenterology services at a hospital outpatient department for a patient being treated by a non-employed physician. This situation may result in increased delays or no access to services, as well as disrupt the continuity of care available to the patient. This is particularly important given the need for early detection and treatment of gastroenterology diseases, such as colorectal cancer.

We appreciate that the Cabinet has maintained its commitment to the responsible and orderly growth of ASC services. For all of the reasons detailed above, we respectfully urge that the SHP be amended to include the above-referenced new Review Criterion for an existing and operating surgery center established under KRS 216B.020 limited to gastroenterology surgical procedures to establish an ASC. Thank you for your consideration of these comments."

(b) Response: The Cabinet appreciates the comments from Anand Gupta, M.D., Paramount Surgery Center, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Representative John C. Blanton, 92nd Legislative District, submitted the following comments:

"Please accept this letter as my written comments on the proposed changes to the Kentucky State Health Plan incorporated by regulation at 900 KAR 5:020. I oppose the proposed changes related to ambulatory surgery centers. The proposed change would allow the establishment of a new surgery center that is majority owned by a hospital if the surgery center is located in the same county as the hospital and the county has more than 30,000 residents without regard to the standard utilization formula otherwise applicable in the Plan. I oppose these changes for the following reasons.

It permits a hospital (along with other investors owning up to 49% of the project) in a rural county meeting the population threshold to place a surgery center very near to a second hospital in the same county even if that second hospital is not physically close to or even in the same town as the first hospital. The new surgery center would drain off the lucrative outpatient surgery revenue from the second hospital. This loss of revenue would cause that second hospital to have to cut back on, or even eliminate, other important but less profitable services offered to the community and reduce the amount of charity care it can provide. In rural Eastern Kentucky, that means long travel times for patients to obtain care elsewhere, and many patients would not be able to do that, meaning that they would go without the care they need.

If COVID-19 has taught us anything, it is that our existing healthcare infrastructure, particularly hospitals, must be preserved. We have also learned that outpatient surgery revenue is a key factor in doing that as we have seen the deep negative financial impact on hospitals that occurred when elective surgeries had to be cancelled all across the state.

While this is an important patient access issue, it is also a regional economic issue for eastern Kentucky. With the demise of the coal industry, healthcare represents an important economic driver for the region, providing good-paying jobs with good benefits. If hospital services are reduced locally due to lack of surgery revenues and patients have to travel outside the region or even outside the state to obtain care, then that is clearly taking desperately needed dollars out of the regional economy.

If the proposed Plan changes on surgery centers are not withdrawn altogether, they should be modified so that hospitals must place these new surgery centers on their own existing campus or adjacent thereto and certainly not be permitted to place a surgery center in a different town near another hospital even if it is within the same county. With this modification, a hospital wanting to start a new surgery center would only be affecting the utilization of its own operating rooms. Not only would that protect another vital hospital in that county, but it would also make it less likely that a hospital would use the new rule to establish a new surgery center for the purpose of selling it later.

It is even more critical that we protect those hospitals that have been designated by the federal government as sole community hospitals. State regulations already recognize that by prohibiting the establishment of freestanding emergency rooms near a sole community hospital. These hospitals deserve the same protection from surgery centers, and the proposed State Health Plan changes are not consistent with that.

I recognize that some of these considerations might not be as significant in the urban counties of our state where there are multiple hospitals close together in the same city, but the effect on rural hospitals should not be ignored. The population threshold of 30,000 seems arbitrary and is well below that of our urban counties. The threshold could easily be adjusted upward to match the density of our urban areas without risking the negative impacts to rural hospitals."

(b) Response: The Cabinet appreciates the comments from Representative John C. Blanton regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Garren Colvin, President and Chief Executive Officer, St. Elizabeth Healthcare, provided the following comments:

"On behalf of St. Elizabeth Healthcare, I am submitting these written comments on the proposed 2020-2022 State Health Plan, 900 KAR 5:020. St. Elizabeth Healthcare does not believe it is appropriate to make substantive changes to the State Health Plan ('SHP') during this period of uncertainty for Kentucky's healthcare providers. Kentucky's providers have effectively managed the COVID-19 crisis. Many lives have been saved through our swift and effective actions. However, Kentucky's providers have suffered unprecedented financial hardship as a result of the cancellation of elective procedures and office visits at

the beginning of the COVID-19 outbreak. Although elective procedures have resumed, volumes have not returned to normal. Making significant changes to the SHP at this time will create harmful uncertainty and could inflict additional financial harm on providers.

St. Elizabeth does not believe that the proposed change to add a new Criterion No. 7 to the SHP criteria for an ambulatory surgical center ('ASC') is justified by the utilization data. Kentucky's Ambulatory Surgical and Hospital Utilization Reports show that every Area Development District ('ADD') in Kentucky has significant excess operating room capacity. In 2018, no ADD had more than 55.7% operating room utilization. The target utilization in the SHP is 85%. Furthermore, according to the SHP need methodology, every ADD had excess operating rooms ranging from three to 89. Copies of graphs showing Kentucky's excess ASC capacity are enclosed with these comments. Without a doubt, the excess capacity throughout Kentucky has only increased with the downturn in procedures resulting from COVID-19.

St. Elizabeth Healthcare is particularly concerned by the requirement in the proposed ASC Criterion No. 7 that the 'applicant hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was four (4) stars or higher for three (3) out of the last four (4) reported quarters preceding the date the application was filed.' St. Elizabeth is strongly in favor of encouraging quality healthcare services, but the Hospital Compare Star Ratings do not accurately reflect the quality of care provided by hospitals. St. Elizabeth agrees with the statement of the American Hospital Association ('AHA') that the 'star ratings approach does not provide an accurate picture of hospital quality performance.' The AHA has shown that the ratings 'are driven by methodology rather than actual hospital performance.' A copy of the February 1, 2019 letter from AHA to CMS is attached to these comments. St. Elizabeth is not aware of any correlation between a hospital's star rating and its ability to operate a quality ASC. For these reasons, Hospital Compare Star Ratings should not be used in the SHP."

(b) Response: The Cabinet appreciates the comments from Garren Colvin, President and Chief Executive Officer, St. Elizabeth Healthcare, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Michael J. Yungmann, President, Mercy Health-Lourdes, provided the following comments:

"I am writing to request that the Office of Inspector General, Division of Certificate of Need, reject proposed changes to the Kentucky State Health Plan Review Criteria for Ambulatory Surgical Centers. Specifically, the Office of Inspector General should reject proposed Review Criterion 7 because it is contrary to the statutory purposes of the Certificate of Need statutes as set forth in KRS 2168.010; it is arbitrary and capricious in contravention of Section 2 of the Kentucky Constitution; it constitutes special legislation in violation of Section 59 of Kentucky Constitution; and it raises

serious compliance issues under the Federal Anti-Kickback Statute, 42 U.S.C. § 1395a-7b(b) and the Stark Law 42 U.S.C. § 1395nn.

Essentially, proposed Review Criterion 7 allows certain hospitals to establish an ambulatory surgical center if it meets certain requirements, without regard to existing outpatient surgical capacity in the county and planning area where the ambulatory surgery center is to be located. Additionally, Proposed Review Criterion 7 is ambiguous and complicated and would run afoul of a number of legal standards.

1. Proposed Review Criterion 7 is contrary to the Legislative Findings and Purposes of the Certificate of Need Statutes.

Proposed Review Criterion 7 allows certain hospitals to expand operations to establish an ambulatory surgical center under extremely complicated, yet liberal, standards without regard to existing out-patient surgical capacity in the area where the ambulatory surgical center is to be established. KRS 216B.010 states the legislative findings and purposes of the Certificate of Need Statutes and states:

> that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth.

Allowing certain hospitals to establish an ambulatory surgical center within the same county where the hospital is located will result in a proliferation of unnecessary healthcare facilities because the criterion does not take into account existing outpatient surgical capacity within the county and area where the ambulatory surgical center is to be located.

2. Proposed Review Criterion 7 constitutes special legislation in violation of Section 59 of the Kentucky Constitution.

Review Criterion 7, in addition to not taking into account existing outpatient surgical capacity within the county where the ambulatory surgical center is to be located, appears to be custom-tailored to accommodate one large health system that has publicly announced plans to establish an outpatient facility that will include an ambulatory surgical center in Lexington, Kentucky. This large health system has publicly announced that it intends to build an outpatient facility with an ambulatory surgical center on the East side of Lexington in the Hamburg area on Polo Club Boulevard. Under existing Review Criteria without the inclusion of proposed Review Criterion 7, such a proposal would not be compliant with the existing standards of the State Health Plan Review Criteria because there is a large amount of outpatient surgical capacity that is, in fact, underutilized in Lexington, Kentucky that would preclude approval of such a proposal. Proposed Review Criterion 7 is simply a special accommodation that would permit this large health system to establish a facility without regard to current outpatient surgical capacity and would clearly constitute an unnecessary proliferation of healthcare facilities and would result in costly duplication and underuse of existing facilities located in Lexington, Kentucky.

3. Proposed Review Criterion 7 raises serious potential compliance issues under the Federal Anti-Kickback Statute and Stark Law.

Proposed Review Criterion 7 contains provisions that permit certain hospitals to own a majority interest in a proposed ambulatory surgical center, but would allow the hospital to establish such an ambulatory surgical center with physicians as a joint venture. The Federal Anti-Kickback Statute Safe Harbors have specific provisions with regard to joint ventures for ambulatory surgery centers between hospitals and physicians. However, Proposed Review Criterion 7 appears to have been drafted without any regard to the provisions of these Safe Harbors. The proposed provisions are extremely complicated and create many ambiguities. Additionally, the proposed Review Criterion 7 creates an opportunity to foster behavior in financial relationships that may run afoul of the Anti-Kickback Statute and Stark Law, both of which prohibit certain physician self-referrals, with the intent of increasing referrals to the proposed ambulatory surgical center based upon these financial relationships. Additionally, the proposed Review Criterion 7 does not address Management Services Organizations that may manage certain ambulatory surgical centers, which are often hospital/physician joint ventures.

(b) Response: The Cabinet appreciates the comments from Michael J. Yungmann, President, Mercy Health-Lourdes, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(4) Subject: Ground Ambulance

(a) Comment: Nancy C. Galvagni, President and CEO of the Kentucky Hospital Association, provided the following comments:

"The Kentucky Hospital Association (KHA) is Kentucky's only state-wide trade association representing the interests of Kentucky's hospitals, health systems, and related organizations. The KHA has the unique authority to speak with a unified voice concerning health policy that affects the operations and viability of Kentucky's hospitals. Following deliberations and debate in accordance with the KHA's governance, the Board of the KHA has approved the following comments for submission to the Office of Inspector General concerning ordinary regulation 900 KAR 5:020 – State Health Plan for facilities and services.

Recommendation: Remove ambulance services from the State Health Plan: By unanimous vote of its Board and Certificate-of-Need Committee, the KHA recommends that ambulance services be removed as a component of the State Health Plan. The members of the KHA believe the current circumstances of the health care environment merit consideration of ambulance services applications under the expedited process of non-substantive review. The KHA believes that the favorable presumptions available

through non-substantive review are appropriate, at this time, for ambulance services. The current demands upon health care services, particularly in light of the current public health emergency caused by the COVID-19 pandemic, justify greater flexibility in the availability of ambulance services. To the extent there is any data indicating that ambulance services may not be needed in a given geographic area, non-substantive review still affords those affected by an application to rebut the presumption of need.

The General Assembly authorized and empowered the Cabinet for Health and Family Services to perform certificate-of-need (CON) functions that 'insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care' by preventing 'the proliferation of unnecessary health-care facilities, health services, and major medical equipment' that 'increases the cost of quality health care within the Commonwealth.' KRS § 216B.010. Achieving a balance between access to quality health care and costly duplication is a dynamic process. Recognizing that the health care needs of Kentuckians periodically change, the General Assembly conveyed upon the Cabinet a mix of duty and discretion – a duty to establish fair review procedures and criteria, combined with flexibility to adapt criteria as necessary.

Accordingly, the General Assembly has given the Cabinet both the authority and discretion to remove ambulance services as a component of the State Health Plan. The CON statutes prohibit the establishment of a health facility without a CON. KRS § 216B.061(1)(a). Formal review procedures apply unless an application has been granted non-substantive review. KRS § 216B.040(1)(a); ACSR, Inc. v. Cabinet for Health Servs., 32 S.W.3d 96, 99 (2000). However, KRS § 216B.095 defers to the Cabinet in determining whether applications for a particular health facility or service will be examined under the non-substantive review process.

KRS § 216B.095(3) identifies various circumstances for which the Cabinet may grant non-substantive review, including changing the location of a proposed health facility; replacing or relocating a licensed health facility; replacing or repairing worn equipment; cost escalations; or industrial ambulance services. The list, however, does not limit the Cabinet's ability to extend non-substantive review for ambulance services generally. The subsection uses the permissive 'may' to convey the Cabinet's discretion as to these enumerated categories and also includes a catch-all provision to extend non-substantive review 'in other circumstances the cabinet by administrative regulation may prescribe.' KRS § 216B.095(3)(f).

The specific reference to 'industrial ambulance services' in subsection (3)(e) should not be construed as a limitation on the Cabinet's ability to grant non-substantive review status to ambulance services generally. Reading the statute in context provides sufficient clarity to show the Cabinet has the authority to grant non-substantive review to ambulance services pursuant to KRS § 216B.095(3)(f). Though unnecessary in light of the statute's unambiguous language, interpretive canons also favor the Cabinet's discretionary authority to grant ambulance services non-substantive review status. First, the disjunctive 'or' in subsection (3)(e) creates an alternative for the Cabinet to extend non-substantive review in the circumstances enumerated 'or in other circumstances the

cabinet by administrative regulation may prescribe.' KRS § 216B.095(3)(f). Second, the canon of *expressio unius* is inapplicable because subsection (3)(a)-(e) 'is not an expression of all' the circumstances in which the Cabinet may grant non-substantive review, particularly in light of the catch-all provision in subsection (3)(f) and because Subsection (7) also adds to the list of health facilities to which the Cabinet may grant non-substantive review. *C.D.G. v. N.J.S.*, 469 S.W.3d 413, 419 (Ky. 2015). Finally, the canon of *ejusdem generis* is also inapplicable for similar reasons, most notably because the enumerated items in (3)(a)-(e) are not of 'the same kind, class, or nature as those specifically enumerated[.]' *Harper v. Univ. of Louisville*, 559 S.W.3d 796, 811 (Ky. 2018). These interpretive canons further support the statute's expression that the reference to 'industrial ambulance services' is illustrative – not exclusive – and does not preclude the Cabinet's discretion to grant non-substantive review to ambulance services generally.

On behalf of the KHA we appreciate your consideration of these comments and hope you will accept the recommendation to grant non-substantive review status to ambulance services by removing it as a component of the 2020-2022 State Health Plan."

(b) Response: The Cabinet appreciates the comments from Nancy C. Galvagni, President and CEO of the Kentucky Hospital Association, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Wade Stone, Executive Vice President of Med Center Health, provided the following comments:

"Med Center Health is aware that some commenters are requesting that the Cabinet remove ground ambulance from the SHP so that future applications for ground ambulance services will receive nonsubstantive review rather than substantive review. Med Center Health is the sole owner of Medical Center EMS, which provides Class I ALS/BLS ground ambulance service in Warren County. In its experience, removing ground ambulance from the SHP would have a negative impact on residents' access to ambulance services in Kentucky.

Formal review of applications for Class I ground ambulance services has worked well in allowing for the addition of ambulance services where they are needed and preventing the proliferation of ambulance services where they are not needed. A review of the Cabinet's records that are available online reveal that over the last decade many more CON applications for Class I ground ambulance services have been approved than disapproved. The records show 22 Class I ground ambulance services have been approved since 2010 while only nine have been disapproved over the same period. This is evidence that formal review of CON applications to establish Class I ground ambulance services is working appropriately.

Warren County has been targeted by those advocating for removal of ambulance from the SHP, but the evidence shows that Warren County would be adversely affected by a proliferation of ambulance services. Warren County residents have access to some of the best ambulance services in Kentucky - at no taxpayer expense. The response times of Medical Center EMS have been consistently well below the state and national averages. Medical Center EMS is one of only three services in Kentucky accredited by the Commission on Accreditation of Ambulance Services. It also been recognized by the American Heart Association for excellence in treating heart attack victims.

The Warren County Fiscal Court passed a resolution on September 23, 2019 stating that 'we are not aware of any Warren Countians who have complained of an inability to access timely Class I Ground ambulance services.' A copy of Resolution #19-18 is being submitted with these comments. The resolution concluded that 'there is no need for an additional Class I Ground Ambulance Provider in Warren County.' The resolution refutes the arguments made by some that counties such as Warren County need more ambulance providers."

(b) Response: The Cabinet appreciates the comments from Wade Stone, Executive Vice President of Med Center Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Jay Chappelle, Vice President of Operations, American Medical Response, provided the following comments:

"Please accept these comments on behalf of Mercy Ambulance of Evansville, Inc. d/b/a Lifeguard Emergency Medical Services and American Medical Response, Mercury Ambulance Service, Inc. d/b/a American Medical Response – Louisville, and Rural/Metro of Southern Ohio, Inc. d/b/a American Medical Response – Northern Kentucky (collectively "AMR"). We write today in strong support of maintaining the Certificate of Need ("CON") Program and the inclusion of Review Criteria in the State Health Plan ("SHP") to ensure the responsible and orderly growth of ground ambulance services in Kentucky.

In Kentucky, AMR serves several counties in Northern Kentucky (Boone, Bracken, Campbell, Carroll, Gallatin, Grant, Kenton, Mason, Owen, and Pendleton Counties), Daviess, Fayette, Floyd, Harlan, Henry, Jefferson, Knott, Leslie, Magoffin, Pike, Oldham, and Trimble Counties. AMR operates both advanced life support and basic life support ambulance services and provides 9-1-1 emergent, 9-1-1 emergent immediate, and non-emergent immediate transports. In Floyd, Johnson, Magoffin, Martin, and Pike Counties, AMR is licensed to provide Class III neonatal inter-facility transports.

AMR is a leading provider of medical transportation, providing services in 40 states and the District of Columbia. Last year alone, AMR performed 4.8 million ambulance

transports. AMR holds contracts for 9-1-1 coverage nationwide and also operates under preferred provider agreements with numerous health care providers throughout the United States, including Kentucky. As a national provider of ambulance services, AMR has a vast knowledge of, and experience with, ground ambulance services CON requirements, particularly those in Kentucky.

Currently, there is a severe shortage of qualified EMTs and Paramedics in Kentucky, as well as across the nation. To compound the shortage of qualified personnel, many of these professionals are leaving the EMS field to work in non-traditional roles, such as hospitals, other health care facilities, and non-health care related industries. According to the Kentucky Board of Emergency Medical Services' ("KBEMS") 2018 Attrition Report, 24% of participating, licensed EMTS and Paramedics are no longer working for a Kentucky ground ambulance service. (KBEMS 2018 Attrition Report, p. 6.) Moreover, in 2018, 22% of participating, licensed EMTS and Paramedics retired, 20% left the profession due to low salary and/or poor benefits, and 54.3% strongly agreed that working in the EMS field is "highly stressful." Id. at pp. 6, 8. As a result of these factors, the supply for qualified EMTs and Paramedics is simply not meeting the demand.

Without Kentucky's CON Program and inclusion of the Ambulance Services Review Criteria in the SHP, there may be a proliferation of unnecessary ground ambulance providers whose services can only be maintained by recruiting staff away from existing providers. Adding more ground ambulance services without the ability to recruit and retain staff will force providers to either reduce services or completely exit the market, leading to a decrease in access to ground ambulance services in Kentucky. This is the exact result that Kentucky's CON Program prevents from occurring.

The CON process for approval of new or expanded ground ambulance services clearly works as intended under the law. This fact is evidenced by the Cabinet's online records, which indicate that, since 2010, more than two-thirds of CON applications for ground ambulance services have been approved under the existing CON process. Currently, a CON application seeking to establish or expand a ground ambulance service in Kentucky is processed through full, formal review. Under formal review, the applicant has the burden of proof to show that the application is consistent with all five of the statutory criteria: (1) Consistency with Plans; (2) Need and Accessibility; (3) Interrelationships and Linkages; (4) Cost, Economic Feasibility, and Resources Availability; and (5) Quality of Services. KRS 216B.040(2)(a)2.a. – e.

If the Cabinet does not maintain the SHP Review Criteria for Ambulance Services, CON applications seeking to establish or expand ground ambulance services would be reviewed under the expedited, non-substantive review process. Under non-substantive review, the need for the proposal is presumed. The affected party, not the applicant, has the burden to rebut the presumed need for the proposal by clear and convincing evidence, a higher burden of proof than the applicant has in formal review. The applicant would no longer have to prove that the application is consistent with the SHP; that is has sufficient interrelationships and linkages in the proposed service area; that it is a financially viable entity that can provide the proposed services in a cost-effective manner, and that it is a

quality provider. Without evidence of an applicant's ability to provide services in a cost-effective and quality manner, the health, safety, and welfare of Kentucky citizens could be compromised. Further, it may result in existing providers unexpectedly exiting the market due to financial constraints, which could limit access to ground ambulance services and potentially impact the ability of existing providers to continue to operate.

It is critical to the life, safety, and welfare of Kentucky citizens that CON applicants demonstrate their consistency with these statutory requirements, particularly out-of-state applicants that have not previously served Kentucky citizens and are not regulated under the licensure standards established by KBEMS. If the CON requirements for out-of-state providers are relaxed, it could result in a proliferation of ambulance services that are not financially viable, and cannot be financially viable in Kentucky, because they do not have appropriate referral sources to implement their proposal. Further, by not having to demonstrate compliance with quality requirements, it may allow certain out-of-state providers with negative licensure and regulatory history to enter the Kentucky market. This includes out-of-state providers that illegally operate in Kentucky in direct violation of Cease and Desist Orders issued by KBEMS.

In other states where CON laws have been repealed or relaxed, the number of ground ambulance services has dramatically increased. For example, in Ohio and Indiana, which do not have CON Programs, there are several ground ambulance services operating in already saturated markets. This has resulted in providers negotiating rates at such low levels so that many cannot sustain long-term operations. In turn, patients' access to quality ground ambulance providers is drastically reduced. Historically, when CON is relaxed or lifted, states quickly experience dramatic growth in the number of ground ambulance services; such growth inevitably leads to CMS and OIG inquiries. These are undesirable results in Kentucky, particularly with a service that is already under certain scrutiny from regulatory bodies.

We appreciate that the Cabinet has maintained its commitment to the CON formal review process for ground ambulance services. For all of the reasons detailed above, we respectfully urge that the SHP remain unchanged as it relates to the CON requirements for ground ambulance services. Thank you for your consideration of these comments."

(b) Response: The Cabinet appreciates the comments from Jay Chappelle, Vice President of Operations, American Medical Response, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Mike Sherrod, Chief Executive Officer of TriStar Greenview Regional Hospital, provided the following comments:

"Please accept these comments on behalf of TriStar Greenview Regional Hospital ('TriStar Greenview') regarding 900 KAR 5:020 and the proposed 2020-2022 Kentucky

State Health Plan ('SHP'). TriStar Greenview agrees with the Kentucky Hospital Association which unanimously voted that criteria for ambulance services should be removed from the State Health Plan. We encourages the Cabinet to remove the review criteria for ambulances from the 2020 – 2022 SHP, as this would improve timely access to emergency medical services.

Background On Greenview

TriStar Greenview Regional Hospital is a 211-bed acute care hospital located in Bowling Green, Warren County, Kentucky. It serves Southern Kentucky and surrounding areas. Recognized by the Joint Commission as a Top Performer on Key Quality Measures®, TriStar Greenview is a national leader in providing quality healthcare. In addition to being accredited by The Joint Commission, the facility is an Accredited Chest Pain Center and a Certified Primary Stroke Center. TriStar Greenview is part of HCA Healthcare, which affords its patients access to an entire healthcare network, no matter what the healthcare need may be.

Position on Removing Ambulance Criteria from the SHP

TriStar Greenview urges the Cabinet to follow the urging of the many health care providers and the Kentucky Hospital Association to remove the ambulance review criteria from the SHP. The only purpose of the minimal criteria (simply a redundant notice requirement) appears to be to require applicants for ambulance CONs to go through the longer and more expensive substantive review process. Requiring a longer and more expensive process to obtain a certificate of need to provide ambulance care is not an approach supported by good health planning, is inconsistent with the approach in other states, and is contrary to the position urged by the KHA. In addition, such a notice requirement is clearly unnecessary as there is already public notice for all CON applicants through the CON newsletter.

Governor Beshear has declared Kentucky to be in a State of Emergency and the President of the United States has declared a national emergency concerning the novel Coronavirus outbreak. During a national health crisis, the Commonwealth should be doing all it can to make vital health care services easier to obtain During this time more than ever, the Commonwealth needs its health care system to function as efficiently as possible and the availability of ambulance services is key to this. As discussed above, failure of timely ambulance transportation means patients who need to get to the hospital cannot, and patients who need to be transferred out a hospital to a different level of care, including to a higher level of care, cannot be transferred out. In the time of bed shortages such as in a flu or coronavirus pandemic, shortage of qualified ambulance providers to move patients to appropriate levels of care harms patients, the health care delivery system's financial viability and ability to respond appropriately to the health care needs of residents of the hospital. Covid-19 has highlighted and exacerbated the need to modernize Class I EMS Certificate of Need to allow adding quality ground EMS Services more easily. EMS Services is one area where Kentucky should move to expand

opportunities of services to add redundancy to the health care infrastructure of the Commonwealth to better meet the challenges of this pandemic and others in the future.

Kentucky is an outlier in requiring CONs for ambulance services. Only three other states (Arizona, New York, and Hawaii) require a CON prior to starting an ambulance service. None of the states surrounding Kentucky require a CON to establish an ambulance service. In fact, the closest state to require a CON for ambulance services is six hundred miles from Kentucky. It is no coincidence that Kentucky also suffers severe shortages in ambulance services. This has resulted in patients having longer wait times for services in numerous instances. Having one ambulance service in a service area as a result of strict Certificate of Need requirements results in a patients stacking up in the emergency room and halls and a monopoly that affects timely delivery of care after the patient arrives at the hospital.

UK HealthCare published a report on August 15, 2019 entitled Community Impact Summary: Transport Impediments to Care Transitions. This report analyzes the difficulties that patients hospitalized in Lexington, Kentucky experience with obtaining ambulance transportation to post-acute care destinations. The report states that '[t]here is only one non-emergent private ambulance service in Lexington, KY. As Kentucky is a certificate of need (CON) state, there is a regulatory hurdle to adding additional ambulances and thus the existing provider controls availability as well as pricing.'[1] As a result, the acute care hospitals have experienced significant delay with patient transports. These routine ambulance delays or cancellations further increase the number of patients who are boarding in the hospitals' emergency departments, which increases health care costs and negatively affects health outcomes. At UK HealthCare, for example, there were 462 avoidable hospital days attributed to ambulance delays from March 2018 through March 2019, which resulted in a hospital cost of $1,195,315.[2] Further, 'increases in hospital stay are associated with mortality, infections, depression, reductions in patient mobility, and an adverse impact on their daily activities.'[3] This report also discusses ambulance delays and the impact of these delays at three other Lexington, Kentucky hospitals (Baptist Health Lexington, CHI Saint Joseph Hospital/Saint Joseph East, and Cardinal Hill Hospital) and concludes that the ambulance delays have a negative impact on the health care system and on patient health.

In addition to this report, Government leaders throughout Eastern Kentucky have also publically assailed both the availability and quality of existing ambulance services. For example, there have been multiple news articles in the last year that include statements from Floyd County Judge-Executive Robbie Williams about Floyd County not receiving adequate ambulance services.[4] There have also been news reports in the last year on Magoffin County Judge-Executive Matt Wireman, a different judge executive in a neighboring Eastern Kentucky county, who described the ambulance services in Magoffin

[1] *Community Impact Summary: Transport Impediments to Care Transitions*, page 3.
[2] Id. at page 4.
[3] Id. at page 4.
[4] August 21, 2019 WCHS article entitled "*Floyd County, KY Officials Worried About Ambulance Response Times";* August 8, 2019 Appalachian News-Express article entitled "*Concerns Voiced Over Ambulance Response in Floyd*."

County as not 'up to par' and totally unacceptable.[5] Daniel Gullet, the Chief of Wheelwright Fire Department Floyd County said the ambulance shortage is 'a matter of life or death.'[6]

This shortage of ambulance services leads to poor consequences for patients. Physician testimony in a recent CON hearing regarding ambulance services in Eastern Kentucky detailed instances where patients could not get timely transportation to receive the care that they needed.[7] The testimony discussed patients at small rural hospitals and at home suffering cardiac events and needing a higher level of care but not being able to get timely ambulance transportation when time mattered the most. For cardiac patients, time is muscle and Kentuckians have lost heart muscle waiting for ambulance transportation. The physician also testified about a leukemia patient in his 30s who died because no ambulance service was available for hours to transport him to a facility that could give him the lifesaving treatment he needs.

Similarly, a November 2019 news story detailed how a six year old child in Northern Kentucky who had to wait two hours for emergency transportation from his local hospital to Cincinnati Children's Hospital after a motorcycle accident because there was no ambulance available.[8] In that case, an Ohio ambulance service just across the river was not allowed to come pick him up because it had no Kentucky ambulance license. It was not able to obtain a certificate of need. This case was so egregious it has resulted in a federal lawsuit challenging the entire certificate of need law in Kentucky.

Multiple complaints filed with the Kentucky Board of Emergency Medical Services throughout the last year include accounts of extreme delays in ambulance transportation. For example, a nurse practitioner who sees patients at dialysis clinics reported of patients waiting multiple hours, in one instance five hours, after dialysis treatment for ambulance transports back to their nursing homes.[9] The complaint also describes instances of patients missing their dialysis appointments because of ambulance transportation being more than four hours late to pick them up.[10] Another KBEMS complaint recounted an incident where an individual with COPD collapsed at a nail salon and turned blue around her mouth. The complaint states that 911 dispatch had to contact the 911 ambulance service 3 times before they arrived more than 35 minutes later, sending a unit from another county.[11] This individual later passed away. Finally, a KBEMS complaint filed by a hospital CEO includes several examples of the hospital requesting ALS transport of patients and the local ambulance service not having an ALS crew available.[12] The CEO's

[5] October 31, 2019 Salyersville Independent article entitled "*Judge-Exec on Ambulance Services: "This is totally Unacceptable*"; November 21, 2019 Salyersville Independent article entitled "C*ounty Holding Lifeguard Accountable*."
[6] August 12, 2019 WKYT article entitled "EMS Staffing Emergency Results in Response Time Delays."
[7] Testimony from Dr. Alexis Salyers on February 19, 2020 in CASE NO. HSAHB CON 19-0035 re CON #098-11-394(34).
[8] November 13, 2019 PJ Media column entitled "*Mandatory Shortages*."
[9] KBEMS Complaint 2019-034.
[10] Id.
[11] KBEMS Complaint 2019-040.
[12] KBEMS Complaint 2019-016.

statement in the complaint says that this 'delays patient care and may put patients' health at risk.'[13] Unfortunately, there are many examples of people having increased morbidity and even mortality due to the unavailability of ambulances in the Commonwealth. This is unacceptable.

Removing these criteria from the SHP will still leave an ambulance applicant subject to review although it would be non-substantive review. KRS 216B.095 (3)(f) clearly authorizes the Cabinet to use its judgment to add any health services to non-substantive review it deems appropriate. It states 'The cabinet may grant non-substantive review status to an application for a certificate of need which is required' to any service enumerated in subsections (a) through (e) and '(f) In other circumstances the cabinet by administrative regulation may provide.' See KRS 2016B.095(3). The plain language of the statute makes it clear that non-substantive review is not exclusively reserved for those services like industrial ambulances and others described in subsections 3(a) through (e). In fact the legislature did not even mandate that the things described in (a) through (e) be made non-substantive because the statute uses the permissive word 'may.'

Any interpretation that ambulances cannot be removed from the SHP and thus be subject to non-substantive review, impermissibly pares the legislature's grant of authority to the Cabinet in contravention of Kentucky law and deviates from the plain meaning of KRS 216B.095(3)(f). Courts have repeatedly ruled that statutes have to be read to give the language its plain meaning. No party may insert language not used by the General Assembly or delete language that actually is used. Clearly, there is no legislative impediment to making ambulances subject to non-substantive review and as set out in our and other commentator's letters, many reasons to make ambulances subject to non-substantive rather than substantive review.

In summary, the shortage of ambulance providers is felt across the Commonwealth. We respectfully urge you to consider the information contained in this letter and the KHA's comments, and to remove the ambulance criteria from the SHP."

(b) Response: The Cabinet appreciates the comments from Mike Sherrod, Chief Executive Officer of TriStar Greenview Regional Hospital, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Janet A. Craig, States and Harbison PLLC, on behalf of Pikeville Medical Center, provided the following comments:

"PMC recommends that the criteria for ambulances be deleted from the SHP. Most other states have already eliminated any certificate of need requirement for ambulance services recognizing that it places an unnecessary barrier to obtaining timely health care services. Only three other states even require a certificate of need to establish or expand an

[13] Id.

ambulance service. PMC and other hospitals routinely experience delays in obtaining patient transport into and out of its facility to the detriment of patient care. Clearly, the faster a patient gets to a hospital after an accident or sudden medical problem, the better the outcome. Similarly, if a hospitalized patient needs a higher level of care than that hospital can provide, time is of the essence in transporting that patient to another hospital that can provide the care they need. Further, even in non-emergent situations, hospitals need the ability to timely return patients to nursing homes when the patient is ready for hospital discharge so as to free up the hospital bed that they were occupying for other patients who need hospitalization. Problems with ambulance response times have been well-documented in news stories in PMC's area and around the state. Litigation is ongoing that is challenging Kentucky's ambulance CON requirement as a result of specific patient detriment due to unavailability of ambulance transport. The CON committee of the Kentucky Hospital Association has voted unanimously in favor of deletion of the ambulance criteria from the SHP.

On March 31, 2020, PMC submitted comments on 900 KAR 6:075 urging the Cabinet to make all ambulance CON applications subject to nonsubstantive review and setting forth the reasons why. A copy of those comments are attached hereto as Appendix A. In its response (attached hereto as Appendix B), the Cabinet did not reject the substantive arguments for why nonsubstantive review would be appropriate. Instead, the Cabinet claimed it would be considered a special regulation and further that the Cabinet lacked the authority to make ambulance CONs nonsubstantive.

It is ironic that the Cabinet would conclude that amending the nonsubstantive review regulation to include ambulances constitutes inappropriate special regulation and then proposes a change to the SHP on ASCs that benefits a few specific hospitals. Regardless, it is clear that deleting the ambulance criteria from the SHP would not be special regulation. Deletion of criteria would apply to all ambulance services. Anyone who wanted an ambulance CON would be on equal footing.

It is equally clear that the Executive Branch has the authority to delete criteria from the SHP. The SHP is defined by KRS 216B.015(28) as 'the document prepared triennially, updated annually, and approved by the Governor.' Further, KRS 216B.040(2)(a) grants to the Cabinet the authority to establish criteria for the issuance and denial of CON's. KRS 216B.040(2)(a)(2)(a) contains some mandates for the content of the SHP related to long-term care beds, but not ambulances.

KRS 216B.095 does not prohibit the deletion of criteria from the SHP or prevent the Cabinet from amending the nonsubstantive review regulation. By listing industrial ambulances as a type of CON application to which the Cabinet may grant nonsubstantive review in KRS 216B.095(3)(e), the General Assembly was not preempting the Cabinet's ability to make ambulances in other classes also subject to nonsubstantive review. KRS 216B.095(3)(f) expressly permits the Cabinet to prescribe nonsubstantive review in other circumstances not listed in sections (a) through (e). Indeed, the Cabinet is not even required to make those things that are listed in (a) through (e) subject to nonsubstantive review because KRS 216B.095(3) uses the permissive word 'may' preceding the entire

list.[14] Thus, the statute neither mandates nor prohibits nonsubstantive review for any CON category. The Cabinet's interpretation impermissibly pares the legislature's grant of authority to the Cabinet in contravention of Kentucky law and deviates from the plain meaning of KRS 216B.095(3)(f).[15] Courts have repeatedly ruled that statutes have to be read to give the language its plain meaning. No party may insert language not used by the General Assembly or delete language that actually is used.[16] Clearly, there is no legislative prohibition or restriction on deleting the ambulance criteria from the SHP.

It should also be noted that the existing criteria in the current SHP are already minimal. The only real requirement is that an applicant document that all agencies licensed to provide ambulance service or medical first response within the proposed service area have been given notice of the applicant's intent to obtain a CON that describes the scope of service and geographic area of the proposed new ambulance service. The other criterion is actually direction to the Cabinet on how to decide cases involving competing applications. The notice requirement is vague. It does not specify the timing of the notice. The notice is also unnecessary. The Cabinet provides public notice of all CON applications through the CON Newsletter. Additional special direct notice is not required for other types of CON applications, moreover, it can be argued that the notice given to all health services in the CON Newsletter meets this criteria making it redundant.

Notwithstanding the minimal nature of the current SHP criteria for ambulances, the fact that there are any SHP criteria means that ambulance applications are subject to the full substantive review process. If these minimal criteria were deleted, ambulance CONs would be subject to nonsubstantive review pursuant to 900 KAR 6:075(3)(a). A key advantage of this process is that ambulance applications could be processed much quicker since nonsubstantive applications can go in the next batching cycle and do not have to wait for an ambulance specific batching cycle. The Cabinet clearly has the authority to do that and the need for additional ambulance services in the Commonwealth is undeniable. Therefore, PMC urges the Cabinet to delete the ambulance criteria from the SHP."

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[14] KRS 446.010(26) specifically provides that "As used in the statute laws of this statute, unless the context requires otherwise: . . . 'May' is permissive".

[15] "Administrative bodies may not add to or pare from the statutory grant of authority," *Camera Center, Inc. v. Revenue Cabinet*, 34 S.W.3d 39, 41 (Ky. 2000), or "by regulation or other action, impose requirements in excess of, or contrary to, those set out in statute." *Natural Resources & Envtl. Protection Cabinet v. Pinnacle Coal Corp.*, 729 S.W.2d 438, 439 (Ky. 1987); *See also Board of Education of Fayette County v. Hurley-Richards*, 396 S.W.3d 879, 889 n. 12 (Ky. 2013) (quoting *Ruby Const. Co., Inc. v. Department of Revenue, Com. ex. Rel. Carpenter*, 578 S.W.2d 248, 252 (Ky. Ct. App. 1978) (citing *Linkous v. Darch*, 323 S.W.2d 850 (Ky. 1959)) ("An Administrative agency may not by regulation 'amend, alter, enlarge, or limit terms of legislative enactment'").

[16] "The first principle of statutory construction is to use the plain meaning of the words used in the statute. *See Revenue Cabinet v. O'Daniel*, 153 S.W.3d 815 (Ky. 2005);" We are not at liberty to add or subtract from the legislative enactment or discover meanings not reasonably ascertainable from the language used." *Commonwealth v. Harrelson*, 14 S.W.3d 541, 546 (Ky. 2000).

(b) Response: The Cabinet appreciates the comments from Janet A. Craig, Stites and Harbison PLLC, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Michael L. Adkins, President, Portsmouth Emergency Ambulance Service, Inc. ("PEASI") and Greenup Emergency Ambulance Service LLC ("GEAS"), provided the following comments:

"Thank you for the opportunity to comment on the proposed revisions to 900 KAR 5:020 and the State Health Plan ('SHP'). Please accept these comments on behalf of Portsmouth Emergency Ambulance Service, Inc. ('PEASI') and Greenup Emergency Ambulance Service LLC ('GEAS') in strong support of maintaining the Ambulance Service Review Criteria in the SHP.

PEASI has operated since May 11, 2011 and provides ground ambulance services in Ohio and Kentucky. In Kentucky, PEASI is licensed to provide Class I ALS/BLS ground ambulance services on a 24-hour, emergency and non-emergency basis in Greenup and Lewis Counties, Class I BLS only ground ambulance services in Mason County for interfaculty emergency transports originating in Mason County, and Class II BLS only non-emergency ground ambulance services in Boyd County. PEASI provides these services from its main base station in Portsmouth, Ohio, another base station in South Shore, Kentucky, and two satellite base stations, one in Lewis County and the other in the eastern part of Greenup County.

GEAS is licensed to operate a Class I ALS/BLS ground ambulance agency in Greenup County, Kentucky. GEAS provides these services on a 24-hour, emergency and non-emergency basis from its main base station in Flatwoods, Kentucky.

PEASI and GEAS strongly support Kentucky's Certificate of Need ('CON') Program and the inclusion of Review Criteria in the SHP for responsible and orderly growth of ground ambulance services that is based on needs in specific geographic service areas and specific factual situations. The CON process is necessary for Kentucky's ambulance industry to maintain its economic viability and stability. KRS 216B.010 delineates the findings and purposes of the CON law:

> Insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and under use of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth.

Maintaining SHP Review Criteria for ground ambulance services satisfies these statutory purposes. In Kentucky, the standards to approve the establishment or expansion of ground ambulance services have remained constant. This is because without the CON requirements for ground ambulance services, there could be a proliferation of unnecessary providers seeking to establish and operate ground ambulance services, which could result in unwanted abuses of the system.

Currently, a CON application seeking to establish or expand ground ambulance services in Kentucky is processed through full, formal review. Under formal review, the applicant has the burden of proof to show that the application is consistent with all five of the statutory criteria: (1) Consistency with Plans; (2) Need and Accessibility; (3) Interrelationships and Linkages; (4) Cost, Economic Feasibility, and Resources Availability; and (5) Quality of Services. KRS 216B.040(2)(a)2.a. – e. By maintaining the Ambulance Service Review Criteria in the SHP, CON applications seeking to establish ground ambulance services will continue to be reviewed under the full, formal review process.

Under the full, formal review process, not only is a ground ambulance services CON applicant required to prove need for the proposal, it is also required to prove that the application is consistent with the State Health Plan, it has sufficient interrelationships and linkages in the proposed service area, it has the financial wherewithal to provide services in a cost-effective manner, and it is a quality provider. It is critical to the life, safety, and welfare of Kentucky citizens that ground ambulance services CON applicants must demonstrate their consistency with these legal requirements, particularly out-of-state applicants that have not previously served Kentucky citizens and are not regulated under the licensure standards established by the Kentucky Board of Emergency Medical Services (‘KBEMS’).

By retaining the Ambulance Service SHP Review Criteria and formal review process for out-of-state providers, it could prohibit a proliferation of unnecessary ambulance services that are not financially viable, and cannot be financially viable in Kentucky, because they do not have appropriate referral sources to implement their proposal. Further, by having to demonstrate compliance with quality requirements, it may keep certain out-of-state providers with negative licensure and regulatory history out of the Kentucky market. This includes out-of-state providers that illegally operate in Kentucky in direct violation of Cease and Desist Orders issued by KBEMS.

Maintaining the Ambulance Service SHP Review Criteria and formal review process also positively impacts existing public, governmental ambulance providers. Public, governmental ambulance providers are funded through tax dollars. They perform the majority, if not all, of 9-1-1 emergency runs at a financial loss. These financial losses are offset by income earned on non-emergent, scheduled transports. By processing and approving new ground ambulance services providers under the SHP and full, formal review process, it keeps the playing field even and discourages new providers from entering the market to ‘cherry pick’ the more profitable non-emergent scheduled transports. Without requiring ground ambulance services CON applicants to comply with

the SHP and proceed through the formal review process, public, governmental ambulance providers could be forced to seek tax increases to offset their financial losses incurred due to an influx of new providers or be forced to cease providing services. Such a result could negatively impact the providers and communities they serve, particularly rural areas in which the public, governmental ground ambulance providers are the sole provider of ambulance services. It may also result in tax increases on Kentucky citizens.

Maintaining the Ambulance Service SHP Review Criteria and formal review process also balances the staffing needs of existing providers with the approval of new providers. Currently, there is a shortage of EMTs and paramedics nationwide, and Kentucky is one of the states feeling the impact. By processing ground ambulance services CON applications under the SHP Review Criteria and formal review process, the proliferation of unnecessary ground ambulance providers that can only be staffed by recruiting personnel away from existing providers is deterred. In turn, this allows existing providers to continue the level services it offers and remain in the market.

Kentucky's CON Program and SHP Ambulance Service Review Criteria contain rigorous standards by which new and additional ground ambulance services are reviewed. It positively impacts existing public and private ground ambulance services, and also affects the health, safety, and welfare of Kentucky citizens for the better. As such, PEASI and GEAS urge the Cabinet to maintain the SHP Ambulance Service Review Criteria and full, formal review process for CON applications seeking to establish or expand ground ambulance services.

Thank you for your consideration of these comments. Please feel free to contact us if you have any questions or need additional information."

(b) Response: The Cabinet appreciates the comments from Michael L. Adkins, Portsmouth Emergency Ambulance Service, Inc. ("PEASI") and Greenup Emergency Ambulance Service LLC ("GEAS") President, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Troy Walker, President, Kentucky Ambulance Providers Association, provided the following comments:

"The Kentucky Ambulance Providers Association (KAPA) membership has over 130 licensed ambulance providers across the state and would like to take this opportunity to show our opposition to any considered changes to the State Health Plan that would change Ambulance CON applications to non-substantive review.

Initially, KAPA did not file comments under the proposed changes because no changes were considered at that time effecting Kentucky EMS services. However in light of efforts by other organizations to propose changes during the comment period, KAPA

would like our position on record as opposing any changes to Ambulance CON application processes.

The vast majority of EMS services across the state operate with support from local government to provide services. Once again a vast majority provide these services with quality and exemplary patient care. To change the CON process would place an undue burden on these providers operating throughout the Commonwealth."

(b) Response: The Cabinet appreciates the comments from Troy Walker, President, Kentucky Ambulance Providers Association, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(5) Subject: Mega Voltage Radiation Equipment

(a) Comment: Michael J. Yungmann, Market President, Kentucky, Bon Secours Mercy Health, provided the following comments:

"The Emergency created by the COVID-19 pandemic has affected so many more individuals than just those suffering from COVID-19. For cancer patients, COVID-19 has also created an emergency. As patients have delayed seeking diagnostic services and accessing treatment, an emergency exists to increase access to important cancer therapies, including radiation oncology. As more fully explained below, we anticipate a tremendous surge of patients needing therapeutic interventions to cure cancer. These patients, however, are likely to be in later stages of cancer and much more complicated and complex due to the lack of early diagnosis and intervention.

For this reason, we propose that the State Health Plan's review criteria for megavoltage therapy programs be amended to create an exception for hospitals with existing medical oncology programs to expand those services to include megavoltage therapy programs. These existing medical oncology programs are already treating patients with cancer. Because of the wave of patients that will undoubtedly occur due to the lack of early diagnosis and intervention, it is necessary to expand services to include this important therapeutic tool to make services available as soon as possible. Because of the COVID-19 crisis, existing radiation oncology programs are and will continue to be overwhelmed.

We propose an exception to the State Health Plan that will confer non-substantive status to applications by hospitals with existing medical oncology programs and will still mean that applicants must still file applications subject to existing statutory review standards.

Accordingly, we propose that the State Health Plan Review Criteria for Megavoltage Radiation Equipment be amended to add the following Criterion 4:

4. Notwithstanding criterion 1, an application to establish a megavoltage radiation service that will be owned by a Kentucky hospital that currently operates an existing medical oncology program shall be consistent with this Plan.

During the COVID-19 crisis, the concerns of the general public in contracting the virus have resulted in many patients going unscreened for cancers and therefore undiagnosed. The following points should be noted:

- The reports of people dying of heart attacks for fear of exposure to the COVID-19 virus is paralleled by individuals with cancer. [1]
- Cancer is a complex set of diseases whose prognoses are influenced by timing of diagnosis and intervention.
- Thousands of cancer deaths will be attributed to the lack of care for reluctance to seek screenings and treatment during the pandemic. It has long been established that early detection saves lives. The Centers for Disease Control and Prevention ('CDC') reports that it is highly likely that the deferral of care will result in harm to the patient, specifically for treatment of cancers.
- In April of this year, cancer surgeries were deferred.[3] With the suspension of non-essential health services and public fear of accessing health care, Covid-19 has disrupted the cancer care continuum, thereby creating an emergency when patients finally seek cancer diagnosis, care, and treatment.
- While the CDC reports that Covid-19 has claimed more than 143,000 lives, [17] in January 2020, the American Cancer Society projected an estimated 606,520 deaths in the United States due to cancer in 2020. [18] That number is certain to increase exponentially with the absence or delay of screening and treatment due to the COVID-19 crisis.
- Radiation oncology providers may find it very difficult to treat the large influx of these cancer patients with the current equipment and radiation oncologists and staff that currently exist in Kentucky. In order to prevent a crisis in cancer treatment due to a large influx of cancer patients, the

[17] Centers for Disease Control, Coronavirus Cases in the U.S., found at: https://www.cdc.gov/coronavirus/2019ncov/cases-updates/cases-in-us.html

[18] American Cancer Society, 2020 Cancer Statistics, found at: https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21590

Centers for Disease control, Potential Indirect Effects of the COVID-19 Pandemic on Use of Emergency Departments for Acute Life-Threatening Conditions — United States, January—May 2020, found at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6925e2.htm

[2] Centers for Disease Control, Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID- 19 Pandemic, found at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-C()VIDcare.html

[3] ProPublica, Cancer Surgeries and Organ Transplants Are Being Put Off for Coronavirus. Can They Wait?, found at: https://www.propublica.org/article/cancer-surgeries-and-open-transplants-are-being-put-off-for-coronavirus-canthey-wait

Cabinet for Health and Family Services should promulgate the proposed exception to criterion 1.

- The Proposed exception for Megavoltage Therapy CON applications will increase access to important therapeutic interventions to address rising incidences of cancer and the effects of delayed diagnosis and treatment.

We appreciate your consideration of this very important proposal as it is a proactive measure to prevent an additional health crisis and emergency for cancer patients."

(b) Response: The Cabinet appreciates the comments from Michael J. Yungmann, Market President, Kentucky, Bon Secours Mercy Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Michael J. Yungmann, President, Mercy Health-Lourdes, provided the following comments:

"I am writing to request that the Office of Inspector General, Division of Certificate of Need consider changes to the Kentucky State Health Plan Review Criteria for Megavoltage Radiation Equipment. This Review Criterion has been in place without change for a very long time. Concern exists that Review Criterion 1 (b), which requires that an applicant document performance of at least 6,000 procedures in the second year of operation, is not reflective of the actual utilization of existing programs and therefore is arbitrary. Because the Review Criterion serves as threshold for certificate of need approval, this arbitrary criterion can prevent approval of a new radiation therapy program even when an applicant is able to document a strong need for a new program with substantial evidence. Because the review criterion prevents approval of applications, it also discriminates against cancer patients who often suffer disability as a result of their cancer and limitation of functional abilities.

1. The Review Criteria for megavoltage radiation equipment should be removed from the State Health Plan and radiation oncology services should be subject to non-substantive review.

This year, the COVID-19 pandemic engendered a healthcare crisis for which the United States and its healthcare system were unprepared. The COVID-19 pandemic and healthcare crisis has resulted in healthcare providers and patients postponing necessary care and treatments so as to avoid the risk of contracting COVID-19 and avoid the risk of spreading the disease to greater numbers of the population. Even at this point, early in the pandemic, relatively speaking, the effects of COVID-19 are having a profound impact upon the diagnosis and treatment of cancer, and this impact will have a lasting effect upon cancer treatment as well as mortality due to cancer. 'Cancer and COVID-19: What Comes Next,' The Chartis Group, April 21, 2020. Due to patients' postponing care, many patients who otherwise would be diagnosed with cancer at an early stage have postponed care,

and therefore cancers that otherwise would be diagnosed and treated at an early stage will be missed. However, eventually over time, these cancers will be diagnosed at a later stage because there's no reason to believe that the actual incidence of cancer has decreased. Editorial, 'COVID-19 and cancer' Science; June 19, 2020 (Exhibit 1).

Due to diagnoses being delayed due to the COVID-19 crisis, treatment will likewise be delayed and cancer treatment programs, including radiation therapy programs, will see declines in the utilization of radiation therapy. Due to this fact, the Review Criteria for radiation oncology and it's threshold requirement that a program perform at least 6,000 procedures at the conclusion of the second year of operation is unrealistic. The number of radiation therapy procedures will decrease due to the lack of diagnoses being made in a timely fashion even though the incidence of cancer will have remained unchanged. However, when patients and the healthcare system resume pre-COVID-19 levels of cancer screenings and surgeries, there will likely be a large spike in the number of cancer diagnoses due to the delay in diagnoses caused by the COVID-19 pandemic. In addition to large spikes in the number of cancer diagnoses due to delay, cancers will be diagnosed at a later stage and will require more intensive therapies and utilization to treat the cancers that were undiagnosed during the pandemic, leading to another health crisis. 'Physicians urge cancer screening to avoid second health crisis,' Modern Healthcare, June 22, 2020. As a consequence, existing radiation oncology programs will see large increases in the number of patients requiring radiation therapy, yet will not be able to accommodate the spike in cases caused by the massive backlog of cancer patients that had not been diagnosed in an earlier stage. Indeed, current radiation oncology providers may find it very difficult to treat the large influx of these cancer patients with the current equipment and radiation oncologists and staff that currently exist in Kentucky and the United States. Moreover, due to precautions necessary to protect patients and prevent the spread of COVID-19, such as social distancing and required sanitary practices, the number of patients that will be able to be treated at a given time will be seriously decreased to limit the potential spread of COVID-19, especially to extremely vulnerable and fragile cancer patients at high risk for serious health events and mortality due to COVID-19.

In order to prevent a crisis in cancer treatment due to a large influx of cancer patients, the Cabinet for Health and Family Services should remove the Review Criteria for megavoltage radiation equipment so as to permit the establishment of new programs under non-substantive review so that the inevitable healthcare needs of this backlog of cancer patients will be met in a timely and efficient manner. Alternatively, the Cabinet for Health and Family Services should lower the standard in Review Criterion 1(b) which requires that an applicant document performance of at least 6,000 procedures in the second year of operation due to the fact that utilization due to lack of diagnosis as a result of the COVID-19 pandemic will necessarily render such a threshold unrealistic given the current state of the healthcare system as a result of the COVID-19 pandemic.

2. Alternatively, Review Criterion 1(b) is not reflective of actual utilization and its procedural threshold should be revised downward.

As the Cabinet for Health and Family Services 2014-2018 Megavoltage Radiation

Reports document, few programs perform 6,000 or more linear accelerator procedures per year. In fact, only three programs reported utilization that averages more than 6,000 procedures per unit in 2018. These three programs include Baptist Health Paducah which reports performance of 12,405 procedures for 2 units (2018); Lake Cumberland Regional which reports performance of 6,466 procedures for 1 unit (2018); and Norton Hospital/Norton Medical Pavilion/Norton Children's Hospital which reports performance of 13,535 procedures for 2 units. Thus, of the 58 linear accelerator units that are operational in Kentucky, only 5 units performed more than 6,000 procedures, which is less than 10% of all the operational units. Even programs that have been operational for many, many years are not operating at the 6,000 procedures threshold. (Exhibit 2)

Requiring an applicant to project performance of 6,000 procedures in the second year of operation is unreasonable when historical performance of existing programs is considered. Utilization is also somewhat difficult to project as there are many factors that may influence utilization including the recruitment timetables for oncologists and radiation therapy specialists. A much more reasoned threshold requirement for second year utilization could be established based upon the average number of procedures that the existing 58 providers performed, which would be approximately 3,810 procedures if based upon 2018 reported performance of linear accelerator procedures. (Exhibit 3) another approach that better reflects actual practice may be to implement a requirement that an applicant serve a certain number of patients as a threshold rather than perform a certain number of procedures.

3. Establishing a reasonable threshold for projected utilization standards for new programs will expand access to radiation therapy.

With slightly more than 521 new cancer cases per 100,000 people, Kentucky has the highest cancer rate in the country. It also has the highest cancer death rate in the country with 198 deaths per 100,000 individuals. The three types of cancer with the highest prevalence (meaning the most people living with a cancer diagnosed either recently or in the past) were breast, prostate, and lung cancer. However, Kentucky's death rate due to lung cancer reflects a strikingly high rate of 66 per 100,000, which is higher than the average death rate from lung cancer in the US which is 42 per 100,000.[1] (Exhibit 4) America's Health Rankings report Kentucky as the 'Least-healthy state with a three year average death rate for all causes of cancer per 100,000 of 234.9.' Once again, Kentucky holds the unfortunate distinction of leading the country in deaths caused by cancer. Establishing a reasonable threshold for Review Criterion 1(b) that has the potential to expand access to cancer treatment is an important factor that could reduce cancer mortality rates.

4. Other States require applicants to meet lower utilization thresholds for Certificate of Need approval.

Several other states that have certificate of need requirements for radiation therapy programs have established threshold utilization requirements at levels lower than Kentucky's 6,000 procedures. For example, Missouri applies a 3,500- procedure standard and New York applies a 5,000- procedure standard. Alaska requires 4,000 procedures and 250 patients. As a result of Kentucky's high mortality rates, a reduced threshold similar to Missouri, Alaska or New York, is justified so that access to new programs will be expanded as a measure to reduce cancer mortality.

5. Review Criterion 3 should be liberalized to permit Kentucky hospitals to collaborate with Academic Medical Centers with comprehensive cancer programs accredited by the American College of Surgeons Commission on Cancer as Academic Comprehensive Cancer Programs.

Review Criterion 3 provides as follows:

3. Notwithstanding Criterion 1, an application to establish a megavoltage radiation service that will be majority-owned (>50%) by a Kentucky hospital accredited by the American College of Surgeons Commission on Cancer as Academic Comprehensive Cancer Programs shall be consistent with this Plan.

This provision should be liberalized to remove the requirement that a megavoltage radiation service must be majority-owned by a Kentucky hospital accredited by the American College of Surgeons Commission on Cancer as an Academic Comprehensive Cancer Program to promote the collaboration by Kentucky hospitals with Academic Medical Centers to expand and enhance cancer treatment throughout Kentucky. Rather than requiring that a Kentucky hospital accredited by the American College of Surgeons Commission on Cancer as an Academic Comprehensive Cancer Program have at least a 50% ownership interest in a megavoltage radiation service, this criterion should be relaxed to provide that a megavoltage radiation service, will be consistent with Criterion 3 if a hospital has a formal affiliation or collaboration agreement with a Kentucky hospital accredited by the American College of Surgeons Commission on Cancer as an Academic Comprehensive Cancer Program. Relaxing the criterion to provide merely for a formal collaboration or affiliation agreement with an academic medical center would help promote the expansion of cutting-edge cancer treatments to hospitals and cancer patients throughout the Commonwealth of Kentucky without the Academic Medical Centers being required to have a majority ownership interest in the megavoltage radiation service at these hospitals. Relaxing this criterion would also permit the expansion of clinical trials in collaboration with Kentucky's two Academic Medical Centers to help promote modern life-saving cancer treatments to all regions of Kentucky, particularly in more rural portions of the state with high incidence of cancer. Undoubtedly relaxing Criterion 3 would be a major step in reducing cancer mortality throughout the Commonwealth of Kentucky by making available the most modern and cutting-edge treatments to all Kentuckians throughout the Commonwealth of Kentucky.

In closing, Lourdes Hospital Paducah respectfully requests that the Cabinet for Health and Family Services consider changing the State Health Plan's criteria for Megavoltage Radiation Equipment in a manner that will be less arbitrary in light of the COVID-19 pandemic and historical utilization of existing providers. Expanding access to treatment in a manner reflective of actual utilization is a reasonable way to improve access to important cancer treatment. Moreover, expanding the ability of Kentucky hospitals to establish comprehensive cancer treatment programs in collaboration with Academic Medical Centers would promote the expansion of cutting-edge cancer treatments to all Kentuckians."

(b) Response: The Cabinet appreciates the comments from Michael J. Yungmann, President, Mercy Health-Lourdes, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Jody Prather, M.D., Baptist Health, provided the following comments:

"Baptist believes that the status quo should be maintained during the COVID-19 pandemic, but if the Cabinet does intend to make changes to the SHP, it should consider modernizing the criteria for megavoltage radiation equipment to reflect the decreasing demand for such procedures and the increased capacity of existing programs. In recent years, the average number of treatments per case prescribed by oncologists has been declining at the same time that programs have been increasing their capacities. The Kentucky Annual Megavoltage Radiation Services Reports for 2014-2018 show that the number of treatments per case has declined at the same time that the number of cancer cases requiring radiation treatment has stagnated in most parts of the state.

In states with CON, the trend has been to increase volume thresholds to reflect the new reality of decreasing demand and increasing capacity. Michigan requires that the applicant project 8,000 equivalent treatment visits for each proposed unit. Tennessee requires existing units in the service area to average 6,000 treatments per unit, and the applicant must project that it will perform 7,688 procedures annually by the third year of service. North Carolina requires an applicant's existing units in the service area to have performed at least 6,750 treatments per unit annually, and the applicant must project that it will perform 6,750 treatments annually by the third year of service. In contrast, Kentucky's outdated criteria requires that existing programs have more than 4,000 procedures per unit and that any new program must project at least 6,000 annual procedures by the second year of operation. These volume thresholds should be increased to reflect the new reality of decreasing demand and increasing capacity. Thank you for consideration of our comments."

(b) Response: The Cabinet appreciates the comments from Jody Prather, M.D., Baptist Health regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Hollie H. Phillips, Appalachian Regional Healthcare, provided the following comments:

"Appalachian Regional Healthcare, Inc. submits for the Cabinet's consideration a change to current State Health Plan review criteria for Megavoltage Radiation Equipment. Since the establishment of the current review criteria, oncological treatment and equipment has markedly advanced. The delivery of radiation is now more precise which allows for higher doses to be administered in a safer manner. This advancement results in fewer radiation treatments for the patient and shorter treatment plans. The medical journal articles submitted with this letter further support our recommendation. Kentucky continues to experience higher incidence and mortality rates than the US. Therefore, the number of megavoltage radiation therapy procedures required to be performed within criterion 1.a. is overstated and excessively restrictive. We propose that language be added to read as follows: 'Notwithstanding criteria 1, 2, and 3, an application to establish a megavoltage radiation therapy program by a licensed acute care hospital in a county with population greater than 30,000 and no existing CON approved or licensed program shall be consistent with this plan.' I appreciate your consideration."

(b) Response: The Cabinet appreciates the comments from Hollie H. Phillips, Appalachian Regional Healthcare, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Wade R. Stone, Executive Vice President of Med Center Health, provided the following comments:

"Megavoltage Radiation Equipment. We are aware that some commenters are requesting that the SHP criteria for megavoltage radiation equipment be relaxed to allow for the proliferation of more radiation oncology programs. If anything, the criteria needs to be strengthened. Kentucky's criteria is the product of an earlier era when radiation therapy programs had less capacity, physicians prescribed a significantly higher average number of treatments per case, and operating costs were much lower. In recognition of the increased capacity, decreasing number of treatment visits per case, and the higher costs of modern radiation programs, higher volume thresholds are warranted than are currently required by Kentucky's current criteria."

(b) Response: The Cabinet appreciates the comments from Wade R. Stone, Executive Vice President of Med Center Health, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(a) Comment: Garren Colvin, President and Chief Executive Officer, St. Elizabeth Healthcare, provided the following comments:

"Although the proposed SHP does not include any changes to the criteria for megavoltage radiation equipment, St. Elizabeth is aware that some commenters are requesting that this criteria be relaxed to make it easier to establish a new program. If the Cabinet for Health and Family Services is going to revise the criteria for megavoltage radiation equipment, the criteria should be strengthened to reflect changes in megavoltage radiation therapy since the last update to Kentucky's criteria.

When Kentucky's current criteria was implemented, there was more demand for radiation procedures and less capacity. In recent years, the average number of treatments per case has been declining at the same time that existing programs have been increasing their capacities. The Kentucky Annual Megavoltage Radiation Services Reports for 2014-2018 show that the number of treatments per case has declined, and the number of cancer cases requiring radiation treatment is basically unchanged. States that have modernized their criteria for megavoltage radiation therapy have imposed higher volume thresholds than required in Kentucky. Michigan requires that the applicant project 8,000 equivalent treatment visits for each proposed unit. Tennessee requires existing units in the service area to average 6,000 treatments per unit, and the applicant must project that it will perform 7,688 procedures annually by the third year of service. North Carolina requires an applicant's existing units in the service area to have performed at least 6,750 treatments per unit annually, and the applicant must project that it will perform 6,750 treatments annually by the third year of service. Any revision of Kentucky's SHP criteria for megavoltage radiation equipment should be along the same lines.

Thank you for this opportunity to comment on the SHP. Please contact me if you have any questions about this important issue."

(b) Response: The Cabinet appreciates the comments from Garren Colvin, President and Chief Executive Officer, St. Elizabeth Healthcare, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(6) Subject: Private Duty Nursing (PDN)

(a) Comment: Evan Reinhardt, Executive Director of the Kentucky Home Care Association, provided the following comments:

"Please accept the following comments on behalf of the Kentucky Home Care Association ('KHCA' or 'the Association') regarding the state health plan. The KHCA is a trade

association representing and serving Kentucky's home health and home care industry. It is a non-profit organization representing over 70 home health agencies covering all 120 counties and includes non-profit, for-profit, health department-based, multi-state and independent agencies. KHCA also represents hospices, private duty agencies, personal services agencies, as well as companies delivering durable medical equipment and supplies. The Association is active on the national level with the National Association for Home Care and Hospice. KHCA appreciates the opportunity to provide comments on this important topic.

In reviewing the state health plan, we would like to focus on the Private Duty Nursing (PDN). Our chief concern with PDN and all services provided to Kentuckians has been and continues to be patient safety. Among the goals we strive for as an industry is that of ensuring services in the home are provided to Kentuckians at the highest possible standard of care. Currently, Private Duty applications are have no criteria contained in the State Health Plan and are therefore evaluated on non-substantive review. This requires a standard of clear and convincing evidence to overcome. As a result, nearly any agency applying for a Private Duty license receives approval. In combination with recent changes to the rules governing Private Duty agencies, this creates an environment where PDN agencies can operate identically to their Home Health counterparts without any of the regulatory standards required of the Home Health agencies. For the following reasons, we request PDN be returned to the state health plan with substantive review requirements and a more robust regulatory structure to ensure care is safely provided to patients.

Recent amendments (in 2019) to the regulations removed the boundary between Home Health and Private Duty Nursing agencies altogether. By eliminating the four hours of continuous care per day previously required, Private Duty Nursing agencies can serve the very same patient served by Home Health agencies, without any of the oversight or standards of care mentioned above. KHCA acknowledges that regulation should not exist for the sake of regulation, but when dealing with frail and vulnerable populations, certain standards of care are necessary to ensure services are provided in a way that never jeopardizes patient safety. These standards should exist regardless of payor source. KHCA would also advocate for restoring the four-hour requirement in order to draw a bright line between short-term/intermittent care and extended care. Because Private Duty Nursing Agencies are not required to follow the Home Health Agency Conditions of Participation (COPs), the current regulations have broadened the scope of services provided by Private Duty Agencies without creating any additional oversight for care delivery.

Loosening restrictions on Private Duty Nursing and increasing the number of agencies providing skilled nursing services has also further diluted a threadbare workforce. The nursing shortage is particularly acute in Home and Community-Based Services (HCBS) because the lower levels of reimbursement hinder our ability to compete with Skilled Nursing Facility and Hospital wages. When combined with an ever-growing number of patients needing care, we have reached a critical point where patient access to care is now being affected by workforce/nursing shortages. Increasing the number of agencies

in the home will increase turnover rates as more agencies fight for fewer nurses. In an already turnover-heavy environment, such a change further affects the ability of existing agencies to serve patients. If increasing access is the goal, KHCA encourages the OIG to study the industry further and discuss how our industry can reduce barriers to care without endangering patient care or straining the workforce further.

KHCA is one of the primary advocacy groups for HCBS. While we share the goal of moving toward a system that allows services to be provided in the home with the fewest possible barriers, our paramount concern remains for those receiving services. After all, the people we serve are the reason Home Health exists. As mentioned above, our Conditions of Participation serve as the backbone of Home Health services and create the minimum standard upon which Home Health Agencies serve their patients. From maintaining continuity of care, to nurse delegation, to patient rights and responsibilities, to documentation standards, the COPs ensure that agencies provide care that is patient-specific, outcome-oriented, and collaborative.

It bears mentioning that some of the agencies interested in entering this space and advocating for loosening the standards to become a Private Duty Nursing Agency have little to no experience in the provision of skilled care to Kentuckians. They have been engaged in providing non-medical services, and we applaud their efforts to advocate on behalf of their clients being served in the community. That said, KHCA encourages the Cabinet and the OIG to consider, as we have discussed above, that allowing these agencies into Kentuckians' homes without requiring them to live up to the minimum standards of care expected of skilled agencies could do those same citizens more harm than good.

We must also address the gaps in care that have been discussed during this process. KHCA very much agrees that there are patients going unserved or underserved. This is not a result of the industry ignoring an unmet need. Home Health Agencies are duty-bound to provide appropriate care to any patient that is eligible for Home Health services. Any legitimate gaps the Home Health Agency network exist because of workforce shortages, ineligibility for services, or other systemic coverage limitations. Home Health Agencies are very eager to serve their patients and do so as expediently as they are able to. But without enough nurses to provide the existing care needs, agencies cannot meet the growing demand for services in the home. Moreover, in the instances where patients in rural settings struggle to find care, increasing the number of providers guarantees only that: more providers. Because of their location and specific needs, these patients are likely to continue to go without the care they need. While money is not a panacea, KHCA would argue that more investment in Home Health is needed as opposed to more providers. Other states, including states with certificate of need (CON) for Home Health, have already begun to rebalance dollars towards HCBS. We urge the OIG and the Cabinet to consider such an approach before taking steps that could exacerbate gaps in care rather than fill them in.

In closing, KHCA would like to take the opportunity to recommend the following changes to the state health plan:

1) Private Duty Nursing be returned to the state health plan and returned to the formal review process.
2) The 4-hour requirement for services in a 24 hour period should be reestablished.
3) Any policies and procedures required of Private Duty Nursing Agencies should also have to meet Home Health industry standard."

(b) Response: The Cabinet appreciates the comments from Evan Reinhardt, Executive Director of the Kentucky Home Care Association, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(7) Subject: Chemical Dependency Treatment Beds

(a) Comment: Joseph Pritchard, President and CEO, Pinnacle Treatment Centers, provided the following comments:

"Thank you for the opportunity to comment on 900 KAR 5:020 and the 2020 – 2022 State Health Plan ('SHP'). Please accept these comments on behalf of Pinnacle Treatment Centers KY-I, LLC ('Pinnacle') and the facilities it operates throughout Kentucky in support of maintaining the Chemical Dependency Treatment Beds Review Criteria. Among the continuum of care services offered in Kentucky, Pinnacle is authorized to provide care in 16 licensed chemical dependency treatment beds in Georgetown, Kentucky.

Pinnacle strongly supports Kentucky's Certificate of Need ('CON') Program and the inclusion of criteria in the SHP for responsible and orderly growth of chemical dependency treatment beds. Pinnacle requests that the methodology for determining need for additional chemical dependency treatment beds be reviewed as it does not adequately address the manner in which substance abuse treatment services must be rendered in Kentucky. One of the issues that continues to arise is the clinical service models required to be used by Medicaid Managed Care Organizations. Given a significant portion of Kentucky residents who seek chemical dependency treatment are Medicaid beneficiaries, the SHP Chemical Dependency Treatment Beds Review Criteria should require an applicant to demonstrate its ability to provide long-term wrap around services as the person progresses through recovery.

KRS 216B.010 delineates the findings and purposes of the CON law:

> Insure that the citizens of this Commonwealth will have safe, adequate, and efficient medical care; that the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and under use of such facilities, services, and equipment; and that such proliferation increases the cost of quality health care within the Commonwealth.

Maintaining SHP review criteria for chemical dependency treatment beds satisfies these statutory purposes. While certain behavioral health services have been expanded in Kentucky to combat the increasing alcohol and substance abuse problems the state is experiencing, the standards to approve additional chemical dependency treatment beds have remained constant and unchanged. This is because without the CON requirements for chemical dependency treatment beds, there could be a proliferation of unnecessary providers seeking to establish these beds, which could result in the same problem the Commonwealth experienced with suboxone clinics. When the issue with suboxone clinics arose, both the Kentucky Board of Medical Licensure and Department for Medicaid Services promulgated regulations to address the abuses.

Often, individuals presenting for treatment have dual diagnoses and require care by qualified individuals. Currently, most of the chemical dependency treatment beds are owned and operated by acute care hospitals. Pinnacle is one of the exceptions. The undersigned has experience in operating substance abuse treatment centers in several states and has seen the negative results that can come with relaxed regulation of chemical dependency treatment beds. New Jersey relaxed its rules and is now trying to restrict additional beds because people in dire need of care were inappropriately placed in hotel-type accommodations with no structured treatment program. Likewise, California has no restrictions and no process to determine whether an entity has the appropriate resources and experience to support a quality system that rehabilitates people.

Currently, a CON application seeking to establish chemical dependency treatment beds in Kentucky is processed through full, formal review. Under formal review, the applicant has the burden of proof to show that the application is consistent with all five of the statutory criteria: (1) Consistency with Plans; (2) Need and Accessibility; (3) Interrelationships and Linkages; (4) Cost, Economic Feasibility, and Resources Availability; and (5) Quality of Services. KRS 216B.040(2)(a)2.a. – e. By maintaining review criteria in the SHP, CON applications seeking to establish such beds will continue to be reviewed under the formal review process.

Under full, formal review, a CON applicant has the burden of proof to show by a preponderance of the evidence that a need exists for its proposal. Further, under formal review, an applicant is required to demonstrate that it has sufficient interrelationships and linkages with existing resources to provide quality care and that it is a financially viable provider. Without evidence of an applicant's ability to provide services in a cost-effective and quality manner, the health, safety, and welfare of Kentucky citizens could be compromised, particularly when the applicant is not required to prove that it has the experience and qualifications to appropriately treat this patient population.

Further, while there are regulations in Kentucky governing chemical dependency treatment services and facility specifications, there is no separate regulation governing the operations and services of a chemical dependency treatment facility. Because of this lack of regulatory framework, it is imperative that the CON requirements for chemical dependency treatment beds remain intact. By maintaining review criteria for chemical dependency treatment beds, the Cabinet may avoid the approval of a plethora of new

chemical dependency treatment facilities, as well as the proliferation of unnecessary, costly services and the underuse of existing services that have capacity to serve additional patients that comes with such approvals. Without CON requirements for chemical dependency treatment beds, there may be a proliferation of providers that use inexpensive, unsupervised lodging for the residential component of care and the provision of out-of-network intensive outpatient therapy at an ultra-high cost. Under this undesired 'Florida Model' of care, patients may unwittingly exhaust their substance abuse benefits or be personally responsible for high private-pay expenses. Such results directly contradict the statutory mandates in KRS 216B.010 and are clearly not in the best interest of the health, safety, and welfare of Kentucky citizens.

Merely providing a bed and medicine fails the patient. A patient entering a chemical dependency treatment facility has the right to expect a safe environment in which counseling and medication-assisted treatment, if appropriate, is offered by qualified and experienced providers. The patient has the right to expect access to a continuum of care to assist him/her in achieving sobriety. By maintaining the chemical dependency treatment beds review criteria in the SHP, new providers entering the market must show their ability to provide appropriate services in a cost-efficient and quality manner. In turn, this may ensure that all individuals in need of substance abuse treatment services, regardless of their payor source, will have access to appropriate services, which may positively impact existing providers and ultimately increase patient volumes. As such, Pinnacle urges the Cabinet to maintain the SHP review criteria and formal review process for CON applications seeking to establish chemical dependency treatment beds.

Thank you for your consideration of these comments. Please feel free to contact me if you have any additional questions."

(b) Response: The Cabinet appreciates the comments from Joseph Pritchard, CEO, Pinnacle Treatment Centers regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

(8) Subject: Acute Care beds to a Behavioral Health Unit for Geriatric Patients.

(a) Comment: Colleen McKinley, Attorney at Law, provided the following comments on behalf of Jennie Stuart Medical Center:

"I write on behalf of Jennie Stuart Medical Center ('JSMC'), which applied for and was granted the above-referenced certificate of need ('CON') to convert twelve acute care beds to a behavioral health unit for geriatric patients. The CON was issued on March 27, 2017, and, following renovations, the unit was opened in December of 2018. A revised license was issued effective August 2, 2018 to reflect that the total licensed bed capacity remained at 194, consisting of 182 acute care beds and 12 psychiatric beds. A copy is attached (Appendix 1).

Now, nearly two years later, the hospital reluctantly has come to realize that there is little to no demand for a dedicated geriatric psychiatric service. Average daily census is 3, and the hospital has never had more than 7 of the beds occupied on a given day. On the other hand, many adults under the age of 65 seek admission to the hospital for psychiatric treatment and must be turned away. For the majority of these patients, Medicaid is the only program on which they can rely for treatment. In an attachment to this letter (Appendix 2) is a demonstration of the problem. Although Christian County has a 97-bed psychiatric facility, Cumberland Hall, 58 of its 97 beds are allocated to children (15), adolescents (23) and a unit for active duty military under contract with the Department of Defense (@20). Severely exacerbating the problem is the fact that Cumberland Hall does not accept Medicaid reimbursement for adult psychiatric inpatients. Adults under 65 with Medicaid insurance who present at JSMC's emergency department with a diagnosis indicating the need for inpatient psychiatric care have to be transferred out of the area. Finally, attached as Appendix 3 is a letter from Eric Embry, CEO of the Pennyroyal Center, Christian County's community mental health center, stating the unmet need for adult psychiatric beds, an unmet need magnified by the current COVID-19 pandemic.

Consequently, following discussions with the hospital's behavioral health professionals, and consultation with the Pennyroyal Center, JSMC has concluded that the path forward is to find a way to remove the restriction to geriatric psychiatric services and the prohibition on applying for Medicaid, so that it can serve adult psychiatric patients, including those receiving Medicaid.[1]

Unfortunately, existing psychiatric bed need criteria in the State Health Plan do not ‘fit’ what the hospital is seeking. For example, it isn't interested in ‘adding’ psychiatric beds or ‘converting’ acute care beds to psychiatric beds, because the beds are already approved as psychiatric beds. Instead, the hospital seeks to remove the exclusive dedication to geriatric patients and the prohibition on Medicaid reimbursement. We would appreciate your advice on how to accomplish the foregoing. Understanding that it may not be possible even to consider our request without amending the State Health Plan, and in the knowledge that consideration of changes to the State Health Plan are currently under way, we offer the following, to be added as a new section of the criteria under II. Behavioral Health Care, A. Psychiatric Beds:

<u>Conversion of Geriatric Psychiatric Unit:</u>

<u>An application to convert an existing non-Medicaid inpatient geriatric psychiatric program to an adult psychiatric unit and seek Medicaid certification, in an existing licensed acute care or critical access hospital, shall be considered consistent with this Plan if the following conditions are met:</u>

<u>1. If the applicant is an acute care hospital, the occupancy of the beds in the applicant's existing geriatric psychiatric unit is at or below twenty-five (25) percent, according to the most recent edition of the Kentucky Annual Hospital Utilization and Services Report, and the unit has been in service for at least one (1) year;</u>

2. If the applicant is an acute care hospital, all of the proposed psychiatric beds are being converted from existing licensed geriatric psychiatric care beds;
3. All of the existing geriatric psychiatric beds converted to adult psychiatric care will remain on-site at the applicant's existing licensed facility;
4. All of the geriatric psychiatric beds converted to adult psychiatric care shall be dedicated to the treatment of adult patients, aged eighteen (18) and older;
5. The applicant shall establish distinct admission and discharge criteria for admitting only those patients whose ages and mental conditions qualify for treatment in a regular adult psychiatric unit;
6. The staff of the unit shall include a multidisciplinary team of specialists involving psychiatry and internal medicine with specialization in the treatment of adults and nursing personnel specially trained in psychiatric and medical patient care; and
7. Adult psychiatric beds that may exist in the county where the applicant is located, excluding state-owned facilities, are not certified to accept Medicaid payment."

(b) Response: The Cabinet appreciates the comments from Colleen McKinley, Attorney at Law on behalf of Jennie Stuart Medical Center, regarding the proposed amendment of the State Health Plan, 900 KAR 5:020.

Please refer to the Cabinet's previous response to the comments submitted by Chris Stevenson (page 12).

V. SUMMARY OF STATEMENT OF CONSIDERATION AND ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The public hearing on this administrative regulation was held on June 22, 2020. The Office of Inspector General responded to the verbal testimony and written comments that were received by the end of the public comment period. The Office of Inspector General will be amending the administrative regulation.

Page 1
Section 2(1)
Line 20
After "Plan", insert "August".
Delete "April".

Material Incorporated by Reference

State Health Plan Cover Page
Edition Date in Top Right Corner
After "Date:", insert "August".
Delete "April".
Edition Date in Middle of the Page
After "(", insert "August".

Delete “April”.

Page 37
III.E.
Review Criteria
Delete the following:
Beds from a public ICF/IID facility shall not be transferred to a proposed or existing private ICF/IID facility.

Page 39
IV.A.
Review Criteria 3.b.
After “comprehensive”, insert “laboratory”.
Delete “program”.

Page 52
V.B.2.
Review Criteria
After “shall be located within”, insert “twenty (20)”.
Delete “thirty (30)”.

Page 52
V.B.3.
Review Criteria
After “that is located within”, insert “twenty (20)”.
Delete “thirty (30)”.

Page 53
V.B.6
Review Criteria
After “1, 2, 3, 4, 5,” insert “and”.
After “7”, delete “and 8,”.

Page 54
V.B.6
Review Criteria
After “with this Plan;”, insert “and”.

Page 54
V.B.7
Review Criteria
After “7”, delete the text of item 7 in its entirety through the number “8”.

Page 54
V.B.8.
Review Criteria

After “1, 2, 3, 4, 5,” insert “and”.
After “6”, delete “and 7,”.