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**, 216B.178**

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 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 "2023 [~~2022~~] Update to the State Health Plan", **July [~~March~~]** 2023 [~~July 2022~~], 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. This material may also be viewed on the Office of Inspector General's Web site at: https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx.

900 KAR 5:020

REVIEWED:

7/11/2023

Date

DocuSigned by:
Adam Mather
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Adam Mather, Inspector General
Office of Inspector General

APPROVED:

7/11/2023

Date

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

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

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation incorporates by reference the current State Health Plan as defined by KRS 216B.015(28) and as required by KRS 216B.040(2)(a).

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.010, 216B.015(28), and 216B.040(2)(a)2.a.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes, KRS 216B.010, 216B.015(28), and 216B.040(2)(a)2.a., by establishing the State Health Plan's review criteria used for determinations regarding the issuance and denial of certificates of need.

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

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: In response to suggestions and comments submitted to the cabinet by interested groups, the amendment to this administrative regulation makes the following substantive changes to the State Health Plan (SHP):

1. Updates the title and edition date of the SHP on page i of the Plan;
2. Updates the Table of Contents on page ii to show deletions and revised page numbers;
3. Updates the title of the SHP on page iii of the Plan under the heading "Purpose";
4. Adds new language to the review criteria on pages 23 and 24 to allow acute care hospitals to convert existing acute care beds to psychiatric beds for adult patients under the following conditions:
   a. The occupancy of acute care beds in the applicant's facility is less than seventy (70) percent according to the most recent edition of the Kentucky Annual Hospital Utilization and Services Report;
      i. All of the proposed psychiatric beds are being converted from licensed acute care beds; and

ii. No more than twenty-five (25) acute care beds will be converted to psychiatric beds;

b. All of the psychiatric beds will be implemented on-site at the applicant's existing licensed facility; and

c. All of the psychiatric beds shall be dedicated exclusively to the treatment of adult patients, aged eighteen (18) to sixty-four (64);

5. Deletes outdated language on page 24 referring to tuberculosis beds. That is no longer a bed category in Kentucky

6. Adds language on page 33 to allow a long-term care pediatric facility to add fifty (50) or fewer beds if:
   a. It is certified under Title XVIII and XIX of the Social Security Act;
   b. It provides high and low intensity nursing facility services to children, including resident admitted to the facility prior to age twenty-one (21) and remain in the facility after reaching age twenty-one (21);

7. Amends language on page 35 to allow an acute care hospital, a critical access hospital, or a nursing facility to establish or expand a home health service to provide services exclusively to their patients who require home health services at the time of discharge;

8. Deletes the criteria on page 47 for megavoltage radiation, thereby making it subject to nonsubstantive review;

9. Deletes the criteria on page 52 for magnetic resonance imaging, thereby making it subject to nonsubstantive review; and

10. Amends the criteria on page 55 for ophthalmological ambulatory surgical centers to:
    a. Allow joint ownership by ophthalmologists with optometrists;
    b. Decrease the time required that the group has been practicing from 10 years to 5 years;
    c. Delete the requirement for a $300,000 investment in laser technology; and
    d. Allow the facility to be located in any county in which one of the owners is located.

In response to comments received during the public comment period, the amended after comments regulation:

1. Amends condition 4.a.ii. above to change the maximum number of beds that may be converted to 20% of the facility's acute care beds up to a maximum of 25 beds;

2. Reinstates the megavoltage radiation equipment criteria in the SHP and removes the requirement for applicants to perform 6,000 procedures after two years;

3. Reinstates the criteria for PET equipment;

4. Reinstates the MRI criteria in the SHP;

5. Amends the review criteria for intermediate care facilities for individuals with an intellectual disability to align with the 2023 passage of HB 334;

6. Adds new language to the review criteria for the addition of therapeutic cardiac catheterizations to allow an applicant to present data showing the number of procedures performed if the cabinet's annual report shows a lesser number due to the practice of combining claims before reporting;

7. Removes the added language and reinstates the existing criteria language for opthalmological ambulatory surgical centers; and

8. Makes conforming changes to the Table of Contents.

(b) The necessity of the amendment to this administrative regulation: This amended after comments regulation is needed to expand health services throughout the state, including rural areas, to enhance immediate access to resources.

(c) How the amendment conforms to the content of the authorizing statutes: This amended after comments regulation conforms to the content of the authorizing statutes because it incorporates by reference the State Health Plan, which is required by statute to be updated annually.

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

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This amended after comments regulation affects entities that submit certificate of need applications and affected persons as defined by KRS 216B.015(3). A total of 81 applications were submitted to the cabinet in calendar year 2022; 70 certificate of need applications were submitted in calendar year 2021; and 60 certificate of need applications were submitted in calendar year 2020.

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

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

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

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

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

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

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

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

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This amendment does not establish or increase any fees.

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

FISCAL NOTE

Administrative Regulation: 900 KAR 5:020
Agency Contact: Kara Daniel
Phone Number: (502) 564-2888
Email: karal.daniel@ky.gov

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

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

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

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate additional revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body during subsequent years.

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

Revenues (+/-):
Expenditures (+/-):
Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? This administrative regulation will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? This administrative regulation will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year? This administrative regulation imposes no additional costs on regulated entities.

(d) How much will it cost the regulated entities for subsequent years? This administrative regulation imposes no additional costs on regulated entities during subsequent years.

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

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]*

This administrative regulation is not expected to have a major economic impact on the regulated entities.

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 State Health Plan, July 2023, 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:

1. Updates the title and edition date of the SHP on page i of the Plan;
2. Updates the title of the SHP on page iii of the Plan under the heading "Purpose";
3. Adds new language to the review criteria on page 24 to allow acute care hospitals to convert existing acute care beds to psychiatric beds for adult patients under the following conditions:
    a. The occupancy of acute care beds in the applicant's facility is less than seventy (70) percent according to the most recent edition of the Kentucky Annual Hospital Utilization and Services Report;
        i. All of the proposed psychiatric beds are being converted from licensed acute care beds; and
        ii. No more than twenty (20) percent of the facility's acute care beds up to a maximum of twenty-five (25) beds will be converted to psychiatric beds;
    b. All of the psychiatric beds will be implemented on-site at the applicant's existing licensed facility; and
    c. All of the psychiatric beds shall be dedicated exclusively to the treatment of adult patients, aged eighteen (18) to sixty-four (64).
4. Deletes outdated language on page 24 referring to tuberculosis beds. That is no longer a bed category in Kentucky.
5. Adds language on page 33 to allow a long-term care pediatric facility to add fifty (50) or fewer beds if:
    a. It is certified under Title XVIII and XIX of the Social Security Act;
    b. It provides high and low intensity nursing facility services to children, including residents admitted to the facility prior to age twenty-one (21) and remain in the facility after reaching age twenty-one (21);
6. Amends language on page 35 to allow an acute care hospital, a critical access hospital, or a nursing facility to establish or expand a home health service to provide services exclusively to their patients who require home health services at the time of discharge;
7. Add new language on page 39 to the review criteria for intermediate care facilities for individuals with an intellectual disability to align with HB 334 enacted during the 2023 session; and
8. Adds new language on page 42 to the review criteria for the addition of therapeutic cardiac catheterizations to allow an applicant to present data showing the number of

procedures performed if the annual report shows a lesser number due to the practice of combining claims before reporting.

The total number of pages incorporated by reference in this administrative regulation is fifty-nine (59).

STATEMENT OF CONSIDERATION
Relating to 900 KAR 5:020

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

I. The public hearing on 900 KAR 5:020, scheduled for May 22, 2023, at 9:00 a.m. in a Zoom meeting format by the CHFS Office of Legislative and Regulatory Affairs was canceled. However, written comments were received during the public comment period.

II. The following people submitted comments:

Name and Title	Agency/Organization/Entity/Other
M. Cristina Atienza, MD	Whitley County Board of Health
Donovan Blackburn President and CEO	Pikeville Medical Center
Daletta Campbell, RN Nurse Administrator	Johnson Magoffin Home Health Agency
Brandy Cantor Executive Director	Kentucky Association of Hospice and Palliative Care
Debbie Carroll Administrator	Professional Home Health Care Agency
David W. Cook President and CEO	Hosparus, Inc. and Affiliates
Jeannie Cundiff Area Vice President of Operations	CenterWell Home Health
Joe E. Ellis, O.D.	Clarkson Eyecare
Liz Fowler President and CEO	Bluegrass Care Navigators
John Franklin, M.D.	Kentucky Academy of Eye Physicians and

President-Elect	Surgeons
Stephanie Gettys, LNHA, CEAL Area Administrator	Interim HealthCare of Northern Kentucky
Ronald Herd, PE	Whitley County Board of Health
Heidi Schissler Lanham Legal Director	Kentucky Protection and Advocacy
Donna Little Director of Health Policy and Regulatory Affairs	Kentucky Hospital Association
Donald H. Lloyd, II President/CEO	St. Claire Health Care
Benjamin Mackey, M.D. President	Kentucky Academy of Eye Physicians and Surgeons
Susan Matherly Administrator-System Director	McDowell Home Health
Annlyn F. Purdon, MBA, MAcc Executive Director	Hayswood Health Services, Inc.
Russ Ranallo Chief Financial Officer	Owensboro Health, Inc.
Marcy Rein, RN, MPH Public Health Director Home Health Administrator	Whitley County Health Department and Home Health Agency
Evan Reinhardt Executive Director	Kentucky Home Care Association
Ryan Smith, M.D. Treasurer/Secretary	Kentucky Academy of Eye Physicians and Surgeons
Wade R. Stone Executive Vice President	Med Center Health
David Williams, MD	Whitley County Board of Health

Anna Stewart Whites, Esq.	Appalachian Hospice and Home Health Services
Michael J. Yungmann President	Mercy Health-Lourdes

III. The following people from the promulgating administrative body responded to the comments:
Name and Title

Adam Mather, Inspector General

Kara L. Daniel, Deputy Inspector General

IV. Summary of Comments and Responses

(1) Subject: Home Health Services

(a) Comment: Donald H. Lloyd, II, St. Claire Health Care, submitted the following comments: "I am submitting these comments concerning the proposed 2023 Update to the State Health Plan ('SHP') on behalf of St. Claire Regional Medical Center. Our comments concern the SHP criteria for CON applications for the establishment or expansion of a home health service.

St. Claire strongly supports the Cabinet's proposed changes to the SHP to allow a hospital to establish or expand a home health agency to provide home health services to patients discharged from its facility. We also strongly support the decision to grant nonsubstantive review to such applications.

We believe the Cabinet's proposed changes to the SHP criteria will positively impact patients. It is very important for hospitals to be able to provide home health services to their own patients. When a patient who is appropriate for home health services cannot be discharged to a home health agency, it is detrimental to the patient and the hospital's operations. Patients benefit from receiving quality care in their own homes when medically appropriate. Moreover, unnecessary delays in discharging patients to home health create backups in hospitals that negatively affect patients during times of high patient volume.

Unfortunately, St. Claire has experienced situations in which home health agencies that are not hospital-based have been unwilling at times to accept patients from the hospital because the agency does not have adequate staff or the agency does not wish to serve patients with certain payors (i.e., Medicaid). We believe that the Cabinet's proposed changes will alleviate many of the issues that hospitals such as St. Claire have experienced when trying to discharge patients to home health.

For those reasons, St. Claire strongly supports the Cabinet's proposed changes to

the SHP criteria for home health agencies."

(b) Response: The cabinet appreciates the comments from St. Claire Health Care. The cabinet will retain the proposed changes to the SHP.

(a) Comment: Donna Little, Kentucky Hospital Association, submitted the following comments: "KHA strongly supports the proposed expansion of criteria to allow hospitals to establish home health to serve any of its discharged patients, rather than just patients in the same county as the hospital. Hospitals continue to have difficulties getting their Medicaid and more complex patients placed in home health, so this is a very positive change for hospitals to be able to provide necessary services and continuity of care to patients."

(b) Response: The cabinet appreciates the comments from KHA. The cabinet will retain the proposed changes to the SHP.

(a) Comment: Donovan Blackburn, Pikeville Medical Center, submitted the following comments: "We support the changes by the Cabinet to 900 KAR 6:075E and 900 KAR 6:075 limiting the number of psych beds that can be converted and the changes to the home health criteria moving it to nonsubstantive review and improving the language allowing hospitals the right to implement home health."

(b) Response: The cabinet appreciates the comments from Pikeville Medical Center. The cabinet will retain the proposed changes to the SHP.

(a) Comment: Evan Reinhardt, Kentucky Home Care Association, submitted the following comments. In addition, Daletta Campbell, Johnson Magoffin Home Health Agency, Liz Fowler, Bluegrass Care Navigators, Stephanie Gettys, Interim HealthCare of Northern Kentucky, Susan Matherly, McDowell Home Health, and Annlyn Purdon, Hayswood Health Services, submitted similar comments: "This letter is written on behalf of the Kentucky Home Care Association and its members ('KHCA'). The KHCA is a trade association representing and serving Kentucky's home health and home care industry. It is a non-profit organization representing nearly 70 home health agencies covering all 120 counties including non-profit, for profit, health department based, multi-state, and independent agencies. It also represents hospices, personal services agencies, and companies delivering durable medical equipment and supplies. KHCA is active on the national level with the National Association for Home Care and Hospice.

KHCA strongly opposes the proposed changes in the State Health Plan and nonsubstantive review regulations that essentially deregulate home health services. The changes enable an acute care hospital, nursing facility, or critical access hospital to establish or expand a home health agency to serve its patients in any county outside the full, formal review process. This could result in the proliferation of unnecessary home health providers in already saturated markets.

Unlike full, formal review, under nonsubstantive 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 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 home health services and potentially impact the ability of existing providers to continue to operate.

With these potential consequences in mind the KHCA does not understand the need for, or reasoning behind, the proposed changes. Since 2014, the Office of the Inspector General's ('OIG') policy has been that a hospital-based home health agency can serve one patient outside its licensed service area without filing a Notice of Emergency Circumstances or CON application. In addition, the proposed changes are much broader than the request made by St. Claire Medical Center ('St. Claire'). In its letter, St. Claire, which already operates a home health agency serving Bath, Carter, Elliott, Fleming, Lewis, Menifee, Montgomery and Rowan counties, requests that it be allowed to expand its home health agency to a service area no larger than the county in which it is located and contiguous counties to serve only its discharged hospital patients for which no referral can be made. This request is far more restrictive than the proposed changes.

The KHCA understands the necessity for patients to receive high quality home health care upon discharge from a hospital. If a hospital is unable to find a home health agency that is capable of taking care of one of its patients upon discharge, we propose that the hospital file a letter with the OIG explaining that it is unable to find appropriate follow-up care and, as a result, will provide that care through its existing home health service. The hospital could meet its patient's needs without the necessity of filing a certificate of need application. Draft language to address the emergency situation is attached. This can be added to the current emergency regulation currently undergoing revision: 900 KAR 6:080 and E, Certificate of need emergency circumstances, filed just last week.

If the proposed language stands, it will effectively deregulate home health services in Kentucky and undermine the integrity of Kentucky's CON laws and process. These laws and the CON program will be studied by a special legislative taskforce over the interim legislative session. It is premature to effect such a sweeping change without legislative input. By enabling acute care hospitals, nursing facilities, and critical access hospitals to establish and expand home health agencies, it will increase the number of agencies without the necessity of meeting the established criteria. It will also compromise the financial viability of existing home health agencies by eroding the patient base with an influx of unnecessary providers.

Kentucky's home health care providers have not seen an increase in their Medicaid rates for at least 15 years. Medicare, typically the payor upon discharge from a hospital, provides a higher rate of reimbursement, thereby subsidizing the inadequate Medicaid rate. Of course, this is not to say that Medicare rates are adequate, but they are higher. Reducing this revenue stream will adversely impact current Medicaid providers who provide needed services to Medicaid recipients and waiver beneficiaries. Because of the inadequate reimbursement, the number of agencies providing this care continues to decrease.

Further, there is a severe shortage of qualified home health personnel in Kentucky. Without Kentucky's CON Program and maintaining home health services under full, formal review, there may be a proliferation of unnecessary home health providers whose services can only be maintained by recruiting staff away from existing providers. Adding new home health agencies without the ability to recruit and retain staff will force existing providers to either reduce services or completely exit the market, leading to a decrease in access to home health services in Kentucky. This is the exact result that Kentucky's CON Program prevents from occurring.

Thank you for the opportunity to provide these comments. Please let me know if you would like to discuss our suggestions or any others that may develop.

Propose a new subsection under 900 KAR 6:080:

(7) Notwithstanding subsections 1 through 6 above, a hospital-based home health agency as defined by KRS 216.935(4) may proceed to alleviate an emergency circumstance exclusively for patients discharged from its facility without first obtaining a certificate of need if:

(a) The hospital-based home health agency is licensed by the Office of the Inspector General to provide the same or similar services necessary to alleviate the emergency;

(b) The patient is discharged only to a county in which the hospital is located or counties contiguous to the county in which the hospital is located;

(c) The hospital-based home health agency notifies the Cabinet in writing on the date on which the patient is discharged of the commencement of the provision of the service required to alleviate the emergency. The Notice shall contain the following information:

1. A description of health care services that will be provided to the person or persons, including proof of eligibility for the service;
2. Statement that other, non-hospital-based home health agencies licensed in the service area to provide the service are aware of the need for the service to be provided to the person and have refused or are unable to provide the service;
3. The steps taken to alleviate the emergency;
4. The location or geographic service area where the emergency service is being provided; and
5. The expected duration of the emergency.

(d) The Office of Inspector General, Division of Certificate of Need, shall acknowledge in writing that it recognizes that an emergency does exist.
(e) The hospital-based home health agency providing the emergency service may continue to alleviate the emergency circumstances without a certificate of need until the emergency circumstance ceases to exist.
(f) The hospital-based home health agency providing the emergency service shall notify the Office of Inspector General, Division of Certificate of Need, within ten (10) days of the date the emergency circumstance ceases and emergency services are no longer required."

(b) Response: The cabinet appreciates the comments from the Kentucky Home Care Association and home health agencies. The cabinet will retain the proposed changes to the SHP.

Kentucky is one of only 14 states that require certificate of need for home health agencies and Tennessee is the only border state that regulates home health services under certificate of need laws. The other states include Alabama, Arkansas, Georgia, Hawaii, Maryland, Mississippi, Montana, New Jersey, New York, North Carolina, Vermont, and Washington.[1]

For additional comparison, it is important to note that private duty nursing agencies – a nearly identical level of care that provides skilled nursing services in a patient's home – have been subject to nonsubstantive review for several years. Private duty nursing agencies are prohibited by 902 KAR 20:370 Section 2(2)(b) from seeking Medicare certification while home health agencies are required to be Medicare certified in accordance with KRS 216.935(4).

Because a home health agency has the right to refuse to accept any patient if it is unable to meet the patient's needs, the cabinet's changes to the SHP and nonsubstantive review regulation that seek to treat hospital-based home health agencies similarly to private duty nursing agencies will help prevent unnecessary delays in patient discharges and improve access to services for patients that independent home health agencies do not accept.

(a) Comment: Debbie Carroll, Administrator, Home Health Care Agency, Inc., submitted the following comments: "On behalf of Professional Home Health Care Agency, Inc. (Professional), a non-profit charitable organization operating a home health agency since 1984, and currently operating in in Laurel, Whitley, Knox and Fayette counties, I am writing to oppose proposed changes to the certificate of need law. Specifically, the proposal to create a new category of nonsubstantive review applications for 'an application by a Kentucky-licensed acute care hospital, critical access hospital, or nursing facility proposing to establish or expand a home health service to serve exclusively patients discharged from its facility' will seriously disrupt the existing home health landscape, harm competition, create barriers to entry for all future independent home health agencies, and potentially put numerous small

[1] https://www.ncsl.org/health/certificate-of-need-state-laws

home health agencies out of business – all with no benefit to quality or accessibility.

The proposed rule would give hospital-based HHAs vertical monopoly power.

Approximately 74% of Professional's patients are referred to it upon discharge from a hospital (based on 2022 and YTD 2023 data). Whitley County HHA, one of several home health agencies operated by local health departments, has similar numbers: 78% of its referrals are from hospitals or nursing homes. Knox County Health Department HHA reports that 69% of its patients are referred incident to discharge from a hospital. We believe these percentages are representative of independent home health agencies across the state, who will be at extreme risk if the proposed rule becomes law.

If the rule giving favorable treatment to hospitals becomes final, we know that hospital systems in our service areas will take advantage of the opportunity, even though that there have been at least two recent applications to add services in Professional's service area denied for lack of need (one in 2017 and the other in 2018, later withdrawn following an appeal and remand by Franklin Circuit Court). Giving hospitals the unrestricted ability to capture their own discharges creates a vertical monopoly that could reduce referrals to independent agencies to a trickle (or, equally troubling, result in cherry-picking of the more profitable patients by hospitals, leaving the smaller agencies to take care of more difficult and less profitable patients.) The inevitable loss of hospital and skilled nursing referrals will be devastating to small, local home health agencies like Professional and the Whitley and Knox County Health Department home health agencies. Why create a rule that will add services in areas where hearing officers have already said there is no need, especially when that will result in the evisceration of long-standing, well-established providers?

The proposed rule will inhibit patient freedom of choice. Hospitals claim that they promote patient freedom of choice when discharging patients to home health, but the reality can be very different. While there is a federal law that requires hospitals, as part of discharge planning, to provide a list of other eligible home health agencies to patients who will need home health care, it does not actually protect patient freedom of choice; to the contrary, it actually causes hospitals to highlight their own agencies in the handout. It backfires. More significantly, there is nothing to prohibit hospital employees, including physicians, from verbally steering a patient to the hospital-owned agency. The largest hospital-based agency in the state has even admitted in a hearing that its employees are coached to do this. Further, hospital personnel will know a patient's payor source and have the ability to steer patients selectively, i.e., direct more profitable Medicare patients to the hospital agency and the less profitable patients to other agencies.

There is no need or demand for this exception

There is already an existing SHP exception for hospitals; it has never been invoked.

The only reasonable policy justification for the current proposal would be to help hospitals assure that care is available to their patients on discharge. However, the CON law already does this. The current criteria state that even if an application is inconsistent with the State Health Plan's need formula for home health, if the facility is a hospital or SNF who can document 'the inability to obtain timely discharge for patients who reside in the county of the facility or a contiguous county' who require home health, it can be approved. Even though this provision has been in the State Health Plan for 5½ years, since October 2017, there have been no applications invoking this provision. This fact alone demonstrates that hospitals are not having trouble accessing home health for their patients being discharged.

There are no systemic advantages to hospital-based home health. One hospital system has been known to claim that there are 'continuity of care' advantages to having their own home health services. But this is an illusion; hospital-based health agencies do not use the same nurses to follow patients from hospital to home. A hospital based HHA will always have different personnel, overseen by different management than the in-hospital services.

Common ownership of a hospital and the HHA provides no actual benefit to the patient. A hospital that is concerned with smooth patient transitions will ensure that its discharge planners communicate freely with any post-discharge providers, who are in the business of ensuring smooth handoffs between levels of care, without regard to who owns them. Professional has excellent working relationships with its referring hospitals, some of whom have designated Professional as a 'preferred provider' of home health and/or provide Professional nurses access to their electronic health record system. Hospitals who are concerned with continuity of care after discharge can always assure that by promoting good working relationships with providers of post-hospital care. Independent agencies can also partner with hospitals to promote the hospitals' value-based care objectives. The only obstacle to cooperation between a hospital and an independent home health agency occurs if the hospital chooses monopolization over cooperation.
No SNF has ever applied for home health. A review of the CON website indicates that there has never been an application for a home health agency by a skilled nursing facility.

Very few hospitals pursue home health applications. In the past 10 years, from January 2013 to the present, there have been only 14 applications for hospital-based home health agencies.[1] Some of them were duplicates and several were abandoned at some point prior to a hearing. There have been no applications by hospitals since 2017. Of the 14 hospital-based applications filed in the past 10 years, seven have been filed by Baptist Healthcare (two of them for Powell County), which operates eight hospitals in the state and already has home health care in

[1] Our count of hospital-based agencies and applicants does not include applications by VNA Health at Home, which is part of the Denver-based KentuckyOne corporate family but is operated by a separate entity out of Ohio rather than any KentuckyOne hospitals. VNA Health at Home has filed three applications since 2013, one of which is currently pending.

approximately 40 counties.[1] Only one other hospital or health system has filed more than one application; Cardinal Hill Hospital applied twice to expand services to Scott County. Its first application never proceeded to a decision and the second was disapproved for lack of need, among other criteria. This record of hospitals seeking to establish or expand home health does not indicate a widespread desire of hospitals to enter home health, other than one health system giant's desire to expand its footprint, without regard to the effect on small, home-grown agencies like Professional.

Previous home health CON applications by hospitals have not been found especially meritorious. Of the 8 hospital-based home health applications filed from 2013 to the present that proceeded to a decision, four were approved and four were disapproved. Each of the disapprovals included a finding that there is no need. So, in 10 years there have been only four hospital home health applications found to meet the need criterion. These data do not support any suggestion that hospital-based home health applications are more meritorious, or in need of special treatment, compared to any other category of applicant.

Approvals in the absence of sufficient need result in closures and layoffs

Unwarranted CON approvals do not result in more patients getting care. Instead, they result in redistribution of patients to the detriment of existing providers. In 2006, applications that Professional opposed were approved in Laurel and Whitley counties. The approved applicant proceeded to establish services in both counties even though Professional filed judicial appeals. Both approvals were ultimately reversed due to violations of due process, and the new entrant ultimately discontinued services in both counties. In the interim between the approvals and the two court decisions, there was significant damage to the existing agencies without a significant increase in the number of patients receiving care. As a result of these approvals, for the first time in its 20+ year history (at the time), Professional had to lay off staff and close an office. Since the new agencies discontinued providing services, Professional's volumes have rebounded to previous levels. Actual experience demonstrates that, absent special circumstances, adding agencies does nothing but redistribute the patient base.

Hospital-based agencies do not address need more effectively

The need formula in the State Health Plan calculates usage in a county compared to overall usage in the state. Because an existing agency can always add capacity by adding more personnel, the Plan standard is that there must be a need to serve an additional 125 or more patients in a county for an applicant to expand an agency into that county, and for 250 or more new patients before a new agency can be allowed. Currently, 19 counties in the state show a need for 125 or more new patients to be served. Of these 19 counties, 17 are served by at least one hospital-

[1] Baptist's 2015 application for Knox, Laurel and Whitley counties, is one of the two referred to earlier that was disapproved in 2017 for lack of need, among other criteria.

based agency. In fact, the six counties with the largest need numbers, three are served by three or more hospital-based agencies. Of all 58 counties with a positive number for potential additional home health patients, 46 are served by one or more hospital-based agencies. These numbers indicate that the presence of hospital-based agencies does not predict higher utilization of (or conversely, a lower level of unmet need for) home health in a county.

Of the 12 home health agencies operating in Fayette County, where Professional operates, five of them are hospital-based home health agencies, yet the State Health Plan still shows an unmet need of 1194 in Fayette County. (Professional's application, which was approved in 2012, was specifically targeted at patients below age 65, a population that it identified as having a particular need. Because of its emphasis on a specific category of underserved patients, Professional has met its projections and reduced the unmet need in that population group).

Home health is already set to expand significantly throughout the state through PACE providers

Under the new PACE (Program of All-Inclusive Care for the Elderly) program, new providers of 'all-inclusive care' are already planned for 110 of the state's 120 counties. PACE is a program designed to provide comprehensive services, which may include home health, to persons age 55 or older who need nursing facility care but can live at home with supports. The attached map, from the DMS website, shows that all but 10 counties in the state have a PACE provider already enrolled or a provider enrollment in process (https://www.chfs.ky.gov/agencies/dms/dca/Documents/PACECountyStatusMap.pdf). So far in 2022 and 2023, PACE providers already have certificate of need approval to provide home health services in 34 counties. All PACE providers are eligible for nonsubstantive review to add home health, under the same regulation, 900 KAR 6:075, that your office is proposing to amend. Only two of these providers have begun operations, both in 2023, so their impact in addressing any home health need that may exist, and on the viability of existing providers, cannot yet be calculated. Opening the door to an additional class of home health providers entitled to nonsubstantive review before the impact of the PACE programs can be measured would be a cavalier policy decision.

More home health agencies means more competition for a scarce resource, nurses

Home health services are nursing care, therapies and aide services, i.e., hands-on care provided by people. An agency's potential to grow is limited only by its ability to employ or contract with people who are licensed and able to provide the services in question. The Kentucky Nurses Association has recently reported that the state has from 12 to 20 percent fewer nurses than it needs, and that Kentucky has one of the highest percentages of nurse shortages in the nation. In addition, the current workforce is aging, overwhelmingly burned out and ready to leave the profession.

Approval of a new agency in a county does not increase the pool of caregivers available; rather it creates competition between agencies for nurses, which can result in an arms race for salaries and increase health care costs overall without changing the overall availability of home health care in a market. In fact, Professional often has hospital-based agencies pass on the chance to admit new patients, and refer them to Professional, due to inability to staff additional cases. More agencies does not equate to more human caregivers.

The proposed rule will not result in greater efficiency in the CON process
Even under nonsubstantive review, an opponent is still permitted to request a hearing and attempt to prove that there is no need for the application in the service area. Nonsubstantive review has generally been used as a vehicle for review of projects that are unlikely to be objectionable, and can be reviewed expeditiously. Home health applications do not lend themselves to nonsubstantive review because need is almost always a highly contested issue for which the parties often offer expert testimony and extensive statistical analyses. A hearing on need also requires fairly extensive evidence to educate the hearing officer about the market, referral trends, the capabilities of existing providers, etc. These hearings often take multiple days in order to fully develop the record. Nonsubstantive review will not eliminate existing agencies' motives or legal right to challenge applications, and attempting to force home health applications into the compressed timetable of nonsubstantive review would be an administrative nightmare, with a strong possibility of producing due process violations and judicial appeals.

For all of the reasons discussed above, Professional Home Health Care agency urges the OIG not to adopt the proposed changes that would allow hospital-based home health agencies to obtain certificates of need under the provisions for non-substantive review."

(b) Response: The cabinet appreciates the comments from Professional Home Health Care. Please see the cabinet's response to the comments from the Kentucky Home Care Association.

(a) Comment: Russ Ranallo, Owensboro Health, Inc. (OHI), submitted the following comments: "OHI also opposes the proposal to revise an existing State Health Plan provision and create a new category of non-substantive review for hospitals and nursing facilities seeking to provide home health to patients who are discharged from their facilities. There does not appear to be a need, or even a strong desire among hospitals and nursing facilities generally, for this change, and the proposal overlooks the fact that a new category of provider is currently under development that is likely to result in an additional home health provider in every county of the state.

There are multiple indicators of a lack of need or general desire for this exception. First, since 2017 the State Health Plan has included an exception to the numeric home health need criteria for hospitals seeking to provide home health to their

discharged patients, and it has never been invoked. The current criteria state that an application by a hospital or nursing facility that can document 'the inability to obtain timely discharge for patients who reside in the county of the facility or a contiguous county' may be approved notwithstanding other criteria in the plan. The new proposal would eliminate the requirement for a hospital to show that its proposal is needed, which is antithetical to the purposes of the certificate of need law, including prevention of the 'proliferation of unnecessary health care facilities [and health services]' KRS 216B.010.

In fact, since 2017 there have been no applications by hospitals to add or expand home health services, and it does not appear that there has ever been an application for home health by a skilled nursing facility.

In general, the home health market is already adequately served by home health, including hospital-based providers. Of the 14 counties where OHI provides home health services, eight show a negative need under the current State Health Plan's need prediction formula, and the remaining six that show a positive need are well below the 125-patient threshold for the expansion of an existing service. That threshold makes sense because an existing agency can always flex up to serve additional patients by adding staff if the demand for home health services in fact turns out to be greater than historical utilization. OHI's home health services are available and freely provided to home health-eligible patients regardless of which facilities they are discharged from, and these patients receive the same quality of home health care as patients discharged from an OHI facility. Similarly, if a patient from an OHI hospital chooses home health care with an agency that is not operated by OHI, our discharge planners will provide the same level of coordination and communication to that agency as they would to an OHI agency.

We also note that converting this category of application to non-substantive review does not seem calculated to reduce administrative burden to the CON Office. In fact, it might increase the administrative burden, since affected parties will still be permitted to challenge the need for a proposal, even under the relaxed standard of review. Home health hearings are almost always about need and can be protracted. Trying to resolve care of these applications in the shortened time frame from non-substantive review will add unnecessary stress to the parties and the hearing officer alike, for no discernable policy benefit.

In sum, the current State Health Plan provides an adequate solution in the unlikely event a facility experiences ongoing trouble placing its discharged patients with home health. The proposed changes to the law would cause proliferation and be unnecessarily disruptive to a system that has yet to understand the effect of new statewide PACE providers on the home health market."

(b) Response: The cabinet appreciates the comments from Owensboro Health, Inc. Please see the cabinet's response to the comments from the Kentucky Home Care Association.

(a) Comment: Marcy Rein, Dr. M. Cristina Atienza, Ronald Herd, and Dr. David Williams, Whitley County Health Department and Home Health Agency, submitted the following comments: "The Whitley County Home Health Agency has served Whitley County as part of the Whitley County Health Department since 1969. We provide skilled nursing, physical therapy, speech therapy, occupational therapy, medical social service, home health aide, and ancillary supplies to our home health patients and accept all payor types. Additionally, we provide home and community-based waiver services.

We write to you to express our concern over the proposed regulation changes to allow hospitals a de facto Certificate of Need to provide home health services. This proposed regulation is in response to a single interest group. It creates a situation that can potentially create unnecessary hospitalizations and reduce patient choice. It fails to consider the negative impact on existing businesses.

A Certificate of Need process already allows for assessing a community's need for these services. Hospitals can and do operate home health services where communities need them. This regulation modification is an unnecessary solution looking for a problem. The only organizations seeking this solution are hospital systems and long-term care conglomerate lobbyists.

In analyzing recent home health referrals that our agency cannot accept, the primary reasons are that the patient is not within our county or the referring physician has not signed an order. We have turned no patient away due to a lack of our capacity to serve.

This regulation will incentivize hospitals to admit patients, potentially unnecessarily, to create the relationship required in the proposed regulation. It will reduce a patient's choice of who provides their home health services because it depends on hospitals to provide information about all available home health providers within the patient's community.

The regulation package only identifies those impacted by this regulation change as entities that submit a certificate of need application, specifically 81 entities in 2022. However, every existing home health agency will be affected by this proposed regulation change. This change has the potential to put the Whitley County Home Health Agency out of business. 61.3% of our 2022 home health admissions came from a hospital or long-term care facility. Specifically, 52.6% of our admissions came from a hospital referral, with the hospital within our county referring the largest number. Our agency stands to lose approximately $1.1 million per year, based on our fiscal year 2022 revenue, should this regulation change be approved. At 26% of our agency's total revenue, losing this home health revenue puts the fiscal solvency of the entire Whitley County Health Department at risk.

We ask that the Cabinet reconsider these proposed regulation changes, which are

unnecessary and damaging to local communities."

(b) Response: The cabinet appreciates the comments from the Whitley County Health Department and Home Health Agency. Please see the cabinet's response to the comments from the Kentucky Home Care Association.

(a) Comment: Jeannie Cundiff, CenterWell Home Health, submitted the following comments: "CenterWell Home Health and our 249 Kentucky employees provided over 11,200 episodes of care in 2022. CenterWell Home Health has a four-star quality rating with CMS and an 89% patient satisfaction rate. Today we are writing in opposition to the proposed changes in the State Health Plan and nonsubstantive review regulations that essentially deregulate home health services.

The changes enable an acute care hospital, nursing facility, or critical access hospital to establish or expand a home health agency to serve its patients in any county outside the full, formal review process. This could result in unnecessary home health providers in already saturated markets. In an attempt to ensure that patients have access to home health care services, we believe these changes focus on the wrong lever to achieve this goal.

In an analysis of our 2023 data, we found patients who were unable to be served was due to a lack of clinician staff not a lack of providers. Nationally, during COVID-19, more than 100,000 registered nurses and nearly 35,000 LPNs left the clinical workforce and by 2027, another 900,000 registered nurses are expected to retire or resign from clinical work[1]. Allowing more providers in home health cannibalizes the available clinical workforce, all of whom have employment openings, and creates a situation where more providers are operating understaffed.

Kentucky has been forward thinking in their approach to healthcare workforce especially with the Kentucky Healthcare Workforce Development law which is in consideration for expansion for a federal model. We believe direct public/private investment in clinical training and education will bring more available clinicians to the workforce and better care to Kentucky citizens.

Additionally, the State is taking up CON issues in an interim task force and we believe important changes like these should be reviewed holistically. We look forward to working with the state on these important opportunities.

CenterWell's successes are built on our focus on our patients, quality clinicians and investment in training, education and technology to ensure high quality individualized care. We look forward to working with you in a proactive and constructive way to meet the home health needs of Kentucky."

(b) Response: The cabinet appreciates the comments from CenterWell Home Health. Please see the cabinet's response to the comments from the Kentucky Home Care

[1] NCSBN Research Projects Significant Nursing Workforce Shortages and Crisis | NCSBN

Association.

(a) Comment: Anna Stewart Whites submitted the following comments on behalf of Appalachian Hospice and Home Health Services: "The 2020-2022 Kentucky State Health Plan for Certificate of Need Review and Standards published by the Kentucky Cabinet for Health and Family Services has specific regulations to guide the long-standing CON process for home health and other specific healthcare providers. The regulation for the review criteria is on pages 34-35 of the SHP.

The SHP stipulates home health agencies have review criteria by where a new agency can receive a CON to expand or a new CON could be granted with the typical additional patient need requirement for existing home health agencies, and third criteria to allow acute care facilities to provide home health services in the county where the facility is located which is determined on a county-by-county basis and contains the typical additional patient need requirements for existing home health agencies. Notwithstanding the first two criteria, home health agencies can meet and may apply to provide emergency care if the application is consistent with the SHP to alleviate the emergency need and an application by a licensed Kentucky acute care hospital, critical access hospital, or nursing facility proposing to establish a home health service with a service area no larger than the county which the facility is located and contiguous counties proposing to service exclusively patients discharged from its facility shall be consistent with this Plan if the facility documents in the last twelve months the inability to obtain a timely discharge for patients who reside in the county of the facility or a contiguous county and who require home health services at the time of discharge.

The review criteria found on p. 35 modify the review criteria for hospitals and nursing homes to permit those entities to establish or expand their existing CON and services to "provide services exclusively to patients discharged from its facility" who "require home health services at the time of discharge."

This action, if approved, is in direct conflict with the ruling CMS has provided and effective November 29, 2019, that provides patients with the ability to make healthcare decisions that are right for them and give them transparency into what used to be an opaque and confusing process. By demystifying the discharge planning process care coordination and the system work better for patients by allowing the patients an active role in their care transition to ensure seamless coordination of care. The Discharge Planning Requirement {CMS-3317-F} revises the discharge requirements that hospitals, inpatient rehabilitation facilities and home health agencies must meet to participate in Medicare and Medicaid programs. It requires the discharge planning process to focus on a patient's goals and treatment preferences.

The rule also implements requirement from the Improving Medicare Post-Acute Care Transformation Act of 2014 that includes how facilities will account for and document a patient's goal of care and treatment preferences. The rule requires the

facility's care team to assist patients, their families or the patient's representative access to information that will help them make an informed decisions about their post-acute care, in selecting a provider by sharing key performance data. This is necessary to help to reduce their chances of being rehospitalized. It also updates one provision regarding patient rights in hospitals, intended to promote innovation and flexibility and to improve patient care.

In Kentucky's rural regions there is often only one hospital in the county or even in multiple counties in the region. Should this proposal be approved this results in most or all the patients discharged from that facility who requires home health to be "patients discharged from that facility." This means that the hospital can expand its services to include the entirety of the eligible home health patients discharged in the county or region.

This will create a monopoly on home health services that excludes the established home health providers in the county or region which have obtained a CON to provide such services and are long standing providers in the community.

A hospital may not provide as full a scope of services as the existing home health agency but will have an improper ability to enroll patients at the time of discharge or even prior to discharge. This enriches the hospital system and takes a toll on patient care.

An example would be the ARH system in Floyd, Johnson, and Pike counties in Eastern Kentucky. The hospital does not provide speech therapy or certain other services to home health patients. Pike County ARH home health ONLY offers Physical Therapy and Nursing. Leaving out the Occupational Therapy and Personal Care services that are needed in the region. These hospitals have a history of putting discharged patients on a "wait list" for home health services that is against CMS regulations. Thus, although the patients may be "enrolled in" the hospital's home health services, they are not actually receiving the ordered services or a full scope of services and in some cases are receiving no services at all, even though they have been discharged, as they sit at home unserved on the wait list and return to their care through emergent and or inpatient care creating more costs associated with the delivery of medical care which is totally against the reason for in home health care services.

Although a hospital is required to have a list of all eligible providers of home health or other services upon discharge, counsel for the hospital and the hospital itself has been unable to provide a copy of such list over the past two (2) years in those counties. Patients and families report to local home health agencies that they were not provided with such a referral list or provided with information to make an informed decision about their care by not being given choice in the matter of who provides their care.

KRS 216B.040(2)(a)2.a. requires the Cabinet '[t]o establish criteria for issuance and

denial of certificates of need [,]' particularly that '[e]ach proposal approved by the cabinet shall be consistent with the state health plan[.]'. Historically CON regulations ensure that the agency making a decision on expansion reviews all relevant evidence prior to doing so, to best protect patient choice and patient care. See, e.g., Mchh v. Cabinet for Health and Family, 214 S.W.3d 324, 326 (Ky. Ct. App. 2007). The proposed amendment to the SHP section on home health and hospital expansion makes such review non-substantive and destroys the opportunity or requirement for a review of patient care and patient choice. This is not in the best interests of patients or their families.

Adoption of this regulation would place Kentucky in Non-compliance with CMS direct regulation to allow a patient a choice to participate in their post-discharge care. This could result in patients returning to the emergency room or a re-admit to a facility by not allowing them a choice in the best provider for their care.

The SHP amendment will result in patients being denied choice as federal law and the Social Security Act requires. Kentucky choosing to go against the regulations set forth could create the possibility of CMS stepping in once agencies cry foul to CMS and ask for interference from the Kentucky legislative appeasement of their largest contributors."

(b) Response: The cabinet appreciates the comments from Appalachian Hospice and Home Health Services. The cabinet notes that the proposed change to the requirements to obtain a CON would not affect a hospital's responsibility to allow patient choice regarding their care. Please see the cabinet's response to the comments from the Kentucky Home Care Association.

(2) Subject: Diagnostic and Therapeutic Equipment and Procedures

(a) Comment: Donna Little, Kentucky Hospital Association, submitted the following comments: "Megavolt Radiation Therapy: The State Health Plan has been amended to delete all criteria relating to megavolt radiation therapy from the SHP, which would make all megavolt applications subject to nonsubstantive review. Yet this appears to be not what the Cabinet intended as 900 KAR 6:075, Section 2(3)(i), proposes a new subsection to grant this status only to Kentucky hospitals as part of their accredited cancer program. KHA supports nonsubstantive review only for in-state hospitals as proposed in 900 KAR 6:075. Megavolt radiation therapy services are expensive and require specialized personnel to provide. It is appropriate to grant nonsubstantive review to allow Kentucky hospitals to include this service as part of their investment in a comprehensive accredited cancer program. It would, however, be damaging to deregulate this service across the board, which could result in proliferation from out of state entities seeking to cherry pick the best insured patients to the detriment of Kentucky hospitals that serve all. Therefore, KHA requests that the Cabinet reinstate the criteria in both the SHP and 900 KAR 6:075 for non-Kentucky hospital applicants. Additionally, the criteria should remove the requirement for applicants to perform 6,000 procedures after two years, since

this was found unconstitutional by the Franklin Circuit court."

(b) Response: The cabinet appreciates the comments from KHA. The cabinet will reinstate the megavoltage radiation equipment criteria in the SHP and remove the requirement from the SHP for applicants to perform 6,000 procedures after two years.

(a) Comment: Michael J. Yungmann, Mercy Health-Lourdes, submitted the following comments: "I am writing to submit comments to the 2023 Update to the State Health Plan, March 2023, Certificate of Need Review Standards, specifically, proposed changes eliminating State Health Plan review criteria for megavolt radiation equipment. Mercy Health-Lourdes is strongly in favor of the proposed changes eliminating State Health Plan Review Criteria for Megavoltage Radiation Equipment, thereby making radiation oncology services subject to non-substantive review. The proposed changes will promote development of comprehensive cancer care services within a single health care system and promote efficiency in care, continuity of care, and quality of care, as well as recognizing modern healthcare delivery models emphasizing value-based care.

Currently, the State Health Plan creates considerable barriers to establishing comprehensive cancer care services within a single health system. The State Health Plan (and the Certificate of Need laws generally) permit health care systems to establish certain cancer care services without a Certificate of Need, such as medical oncology programs, cancer surgery programs, and various ancillary and support programs such as nutritional care for the treatment of cancer patients. It is established that, conservatively, approximately fifty percent (50%) of cancer patients will require radiation therapy treatment as part of their cancer treatment to successfully treat the cancer and return the cancer patients to recovery. Under the current State Health Plan, many of these patients undergoing treatment for cancer are required to change health care systems/providers to a completely different health system in order to receive radiation therapy to complete a comprehensive course of cancer treatment. Forcing a patient to 'step out' of a health system that they have chosen for care and with which they are comfortable, particularly in such a challenging and complex path as cancer treatment, and go into another health system for part of their cancer treatment, is terrible for patient experience.

Equally important are the efficiencies of having a comprehensive cancer program within one system in the age of value-based care. For example, physicians and other health care providers can only be members of one Accountable Care Organization ('ACO') which can lead to disjointed care when patients have to change health systems/providers to receive needed radiation therapy. Additionally, different health systems often have different Electronic Medical Records ("EMR") systems that are often not capable of 'communicating' effectively with each other, which can also lead to disjointed care and clinical inefficiencies. A comprehensive cancer care program within one health system increases quality and improves outcomes due to coordination of care, and better communication and

documentation, which leads to improved efficiencies and decreasing costs, which is one of the objectives of the Certificate of Need program, and this is especially the case for 'coved lives' within a health care system's ACO.

Mercy Health-Lourdes has an ACO and Clinically Integrated Network of more than 10,000 lives, and also participates in Medicare Shared Savings Plans and Medicare Advantage Plans (which now comprise more than 40% of our Medicare participating patients, with continued growth). As part of these programs, we are charged to reduce costs and improve quality. These are key drivers of financial performance as we assume greater risk in caring for empaneled patients and have significant sums associated with quality performance. Having in-network providers is a key to success in these programs and requiring patients to go to an out-of-network provider for radiation therapy negatively affects these goals. Having a comprehensive cancer program with radiation therapy is required to effectively navigate the rapidly growing shift in healthcare delivery from pay-for-service to assuming population health risk based on performance.

Kentucky's cancer statistics demonstrates a need for comprehensive, efficient cancer treatment programs. Kentucky had 18.1 cancer deaths per 100,000 population in 2021, which is the third highest in the United States. Cancer is also the second leading cause of death in Kentucky. Radiation therapy is considered best treatment for cancers such as pancreatic, lung, liver, prostate, bladder and cervical cancer. It is also estimated that Kentucky will have 30,270 new cancer cases and 10,090 cancer deaths in 2023. And, specific to the region we serve, while 5-Year trends in incidence rates and mortality rates have decreased both nationally and in Kentucky; -0.9 and -2.0 and -.9 and -2.4, respectively, the counties in Western Kentucky have lagged considerably with average 5-year trends in incidence rates and mortality rates decreasing at much slower rates; -0.1 and -0.7. This shows the area we serve to be improving in both incidence and mortality at a much slower rate than positive trends nationally and statewide. Clearly, comprehensive care needs to be more accessible to patients in Kentucky.

Finally, at the very least, the Cabinet for Health and Family Services must, if not fully adopting the proposed changes in the State Health Plan Review Criteria for megavoltage radiation equipment, making radiation oncology services subject to non-substantive need, revise current standards for approval of a Certificate of Need for megavoltage radiation equipment to acceptable and modern levels. At present, the current threshold of 6,000 treatments per year per machine within the first three years of operation is completely out of step with modern radiotherapy trends. In the latest 2021 state data, of the 62 CON approved megavoltage radiation units in Kentucky, they averaged a total of 3,706 treatments per year per machine – and 3,698 treatments per year per machine over a five-year average. And, of the 62 megavoltage radiation units in Kentucky in 2021, only 5 achieved treatments over 6,000 – the other 57 units in the state failing to meet the set threshold.

In closing, Mercy Health-Lourdes respectively requests that the Cabinet for Health

and Family Services adopt the proposed changes in the State Health Plan eliminating State Health Plan review criteria for megavoltage radiation equipment, thereby making radiation oncology services subject to non-substantive review."

(b) Response: The cabinet appreciates the comments from Mercy Health-Lourdes. Please see the cabinet's response to the comments on megavoltage radiation equipment from KHA.

(a) Comment: Donna Little, Kentucky Hospital Association, submitted the following comments: "PET scans: In 900 KAR 6:075, Section 2(3)(j), the Cabinet has proposed to move all positron emission tomography (PET) applications to nonsubstantive review but has maintained the PET criteria in the SHP, which would keep all applications under formal review. A PET scanner is most commonly used in relation to cancer treatment to select the best treatment approach and monitor how well the cancer responds. Therefore, it would only be appropriate to deregulate PET scanners in the same way as for megavolt radiation therapy, which is to grant nonsubstantive review status only to licensed Kentucky hospitals as part of their comprehensive accredited cancer program. A further deregulation of all PET applications moving into nonsubstantive review is not appropriate and, based on what has occurred in other states, could easily result in an oversupply of scanners not associated with hospital accredited cancer programs, increased utilization and costs, poor quality, and fragmented care for patients. Therefore, KHA recommends providing nonsubstantive review for in-state hospitals only, consistent with the changes for megavolt radiation therapy."

(b) Response: The cabinet appreciates the comments from. The cabinet will reinstate the PET criteria in the SHP.

(a) Comment: Donna Little, Kentucky Hospital Association, submitted the following comments: "MRI: Like megavolt radiation therapy, the State Health Plan has been amended to delete all criteria relating to magnetic resonance imaging (MRI) equipment, which would appear to make all MRI applications subject to nonsubstantive review. Further, 900 KAR 6:075, Section 2(3)(k) proposes nonsubstantive review for MRI applications by any applicant that will be accredited by the American College of Radiology within twelve (12) months of licensure.

However, there is a question as to whether the removal of MRI from the State Health Plan would instead make MRI applications exempt from CON, rather than placing them under nonsubstantive review. Language contained in KRS 216B.020(1) grants exemptions from CON to a variety of services including '...special clinics, including but not limited to wellness, weight loss, family planning, disability determination, speech and hearing, counseling, pulmonary care, and other clinics which only provide diagnostic services with equipment not exceeding the major medical equipment cost threshold and for which there are no review criteria in the state health plan...'. KHA believes this language was used in the past by entities to acquire an MRI outside of the CON process during a window of time when MRI

was briefly not included in the State Health Plan. Also, while freestanding MRIs should be licensed under 902 KAR 20:275, Freestanding or mobile technology, and thus are required to obtain a CON for the establishment of a health facility subject to licensure, this could be interpreted as being overruled by the special clinic exemption provision.

Many of KHA's rural hospital members are concerned with exempting MRI from CON. These hospitals have invested millions of dollars in state-of-the art MRI equipment and are concerned that MRIs established by non-hospital entities (often with inferior equipment) would be established to cherry pick the most profitable patients, leaving hospitals to serve Medicaid and the uninsured. This drain of revenue will only put a further strain on already struggling rural hospitals.

In light of the unintended consequences that may occur from removing MRI from the State Health Plan, KHA requests that the Cabinet re-instate the MRI criteria in the Plan until further discussions occur and there is time for a more deliberative approach to modernize the CON program while addressing the concerns of rural hospitals.

KHA is in the process of developing a plan to modernize the Certificate of Need program for Kentucky and will have its modernization report and proposals completed in June. Once completed, KHA will be sharing those proposals with the Cabinet for Health and Family Services and the General Assembly. Thus, KHA recommends limiting deregulation of MRI until after KHA completes its CON modernization plan and shares it with the Cabinet. If an immediate change must be made now, it should be limited to nonsubstantive review for MRI applications only for existing in-state hospitals."

(b) Response: The cabinet appreciates the comments from KHA and agrees with its recommendation. The cabinet will reinstate the MRI criteria in the SHP.

(a) Comment: Donovan Blackburn, Pikeville Medical Center, submitted the following comments: "Prior to the proposed revisions, the SHP contained criteria for MRI, Megavoltage Radiation and PET equipment. While MRI, Megavoltage Radiation Equipment and PET are necessary for hospitals like PMC to deliver the full range of services their patients require, these pieces of equipment are expensive and often constitute major medical equipment as defined in KRS 216B.015(17). Removing MRI and Megavoltage Radiation Equipment from the SHP throws them in nonsubstantive review and allows any independent entity or provider to more easily acquire them to compete with and undercut the services provided by local hospitals. Likewise, creating a non substantive review category for everyone for PET in 900 KAR 6:075 creates a similar negative effect. Hospitals rely on ancillary services such as MRI, Megavoltage Radiation, and PET to help balance the bottom line. Moving these services to nonsubstantive review by removing any criteria from the SHP for MRI and Megavoltage Radiation equipment and creating a non sub exception for all PET applicants, defeats the Legislature's stated motive for CON

law—avoiding the unnecessary proliferation of health care services. Accordingly, PMC requests that the criteria for MRI, and Megavoltage Radiation Equipment, be left in the SHP, but that an exemption be added to each category of service criteria for MRI, Megavoltage Radiation Equipment and PET that clearly states the criteria do not apply to licensed hospitals. Also, to simplify the CON process, amend 900 KAR 6:075 to add a non substantive category limited to hospitals acquiring a MRI, Megavoltage Radiation Resonance, or PET equipment.

Hospitals like PMC have to offer a full range of services. Some of these services produce a loss. Hospitals can only afford them because of other necessary ancillary services. Ancillary services include MRI, Megavoltage Radiation Equipment and PET equipment. Allowing other applicants to pick up these often profitable ancillary services while not being required to offer the other services that are not as profitable or that even operate at a loss damages the ability of the hospital to provide those services which are necessary for the health and wellbeing of those in the service area. This type of cherry picking is detrimental to the health care delivery system and should not be supported by the Cabinet."

(b) Response: The cabinet appreciates the comments from Pikeville Medical Center. Please see the cabinet's response to the comments from KHA on MRI, PET, and megavoltage radiation equipment.

(a) Comment: Wade R. Stone, Med Center Health, submitted the following comments: "Our comments concern the SHP criteria for megavoltage radiation therapy equipment, which the Cabinet has proposed to delete from the SHP entirely. We believe that removing radiation therapy equipment from the SHP would be a mistake. Megavoltage radiation therapy (MVRT) programs are very costly to establish and maintain. In addition, specialized personnel must be hired to operate and maintain the equipment. Quality and safety must be paramount when using this technology. Consequently, proposals to establish MVRT programs in Kentucky warrant careful consideration.

We believe the existing SHP criteria ensure that new MVRT programs will not be underutilized. The criteria also ensure that for-profit providers will not establish MVRT programs for the purpose of cherry picking the patients with the best insurance from safety-net providers.

We understand that the Franklin Circuit Court has ruled that the 6,000-procedure threshold criterion is unconstitutional in a decision that has been appealed to the Court of Appeals. We believe that specific criterion could be changed to read: 'The applicant shall demonstrate that sufficient need exists so that the proposed program will not be underutilized.' The rest of the criteria should remain in effect."

(b) Response: The cabinet appreciates the comments from Med Center Health. Please see the cabinet's response to the comments from KHA on megavoltage radiation equipment.

(a) Comment: Russ Ranallo, Owensboro Health, Inc. (OHI), submitted the following comments: "OHI opposes the proposal to remove radiation therapy from the State Health Plan, as well as any category of non-substantive review of applications to provide radiation therapy 'by an applicant that is majority owned by a Kentucky-licensed acute care hospital accredited by the American College of Surgeons Commission on Cancer.'

Radiation therapy is the most expensive individual category of service to provide that is regulated in Kentucky certificate of need law. Recent applications have ranged in cost from $4.2 million to as much as $9 million with escalations after a project is fully implemented. This is truly a service for which unnecessary proliferation increases the cost of health care. There are 41 CON-approved radiation therapy facilities that are well-distributed throughout the state. Further, a facility that already has radiation therapy can generally expand its capacity with either no review or non-substantive review, with significantly less investment than the cost involved in establishing an entirely new program. The current standards in the Plan that require, not only satisfaction of a need formula, but also the ability to meet a volume expectation that justifies the enormous investment, are sound from a policy perspective and promote the goals of KRS 216B.010. There is no policy reason for broadly deregulating the establishment of new programs, even where hospitals are involved.

Even if radiation therapy remains in the State Health Plan, we also oppose the proposed addition of a new category of non-substantive review for radiation therapy services that are majority-owned by a hospital. As proposed this rule would impose no geographic limits on the potential for a hospital to establish new radiation therapy services, either on its own or through joint ventures with other investors. This seems likely to lead to costly arms races in which well-funded hospital systems seek to establish facilities where they can take away market share from existing providers, thereby redistributing patients and driving up costs rather than actually improving access."

(b) Response: The cabinet appreciates the comments from Owensboro Health, Inc. Please see the cabinet's response to the comments from KHA on megavoltage radiation equipment.

(3) Subject: Ambulatory Surgical Centers

(a) Comment: Joe E. Ellis, Clarkson Eyecare, submitted the following comments: "There is a clear and increased demand for eyecare in the Commonwealth and the United States. By the year 2030, the population over age 65 will represent 21 per cent of the United States population. In the year 2020, the over 65 age population was already at 17.2 per cent in the Commonwealth, so very likely Kentucky will exceed this projected national average of 21 per cent.

Also, we in Kentucky are already experiencing a shortage of active ophthalmologists and optometrists and this shortage is projected by all accounts to worsening over the next two decades as many Baby Boomers retire from practice. We already are already having an urgent demand for retina and corneal specialists in Kentucky. Over fifty per cent of Ophthalmologists in Kentucky are in practice in Jefferson and Fayette Counties.

As we discussed recently, the Co-Management of Ophthalmic Postoperative Care concept and practice in eyecare in the United States and Kentucky is well established since the early 1980s. The process of Co-Management in eyecare has had thoroughly documented scrutiny over the past few decades. There are many existing transparencies that are in place to allow a patient to choose their best option in eyecare, especially patient choice in eye surgeons and facilities to provide that eye care. Any arrangements for eye surgery require full disclosure of cooperative arrangements. This includes fees not covered by health plans for premium intraocular lenses for cataract surgery.

The Anti-Kickback Statues have also been in place for many decades in eyecare. Again, this has been reviewed over the last few decades with special attention specifically to Co-Management arrangements between Optometrist and Ophthalmologists. There have been very few such issues nationally about violations of Anti-Kickback Statue violations in eyecare. Recent cases of violations in Texas and Tennessee were obviously cases of malfeasance by Ophthalmologists.

As you are well aware, CMS has been studying the current Hospital Outpatient Prospective Payment System (OPPS) versus the use of Ambulatory Surgical Centers (ASCs). CMS is encouraging outpatient surgeries to move to ASCs. The eye surgery only ASCs are projected to save the healthcare systems in the Commonwealth millions of dollars in cataract surgeries, especially large savings in retina and cornea surgeries.

Typically the difference in cost between OPPS and ASC is around $1000 per procedure for cataract surgery, retina surgery and cornea surgery. Rough estimates around the greater Lexington area alone, include about 5000 various cataract, retina and cornea procedures yearly that are performed and billed thru the Hospital Outpatient Prospective Payment System.

Thanks again for your time recently and the time to comment. Hopefully, changes can be made to make eye care more accessible, more cost effective and improve quality in the Commonwealth of Kentucky."

Dr. Ellis submitted a second set of comments as follows: "A few comments, we would suggest to allow all potential eyecare providers to participate in development of eyecare only ASCs. We suggest allowing any ophthalmologist or an ophthalmology group or an ophthalmologist-optometrist group to have no restrictions on percent of ownership allowable and no restrictions on the minimum

number of years of practice a provider has to have to participate in an ASC. Especially in rural areas having a certain percentage of ophthalmologist owners may be problematic. For example, there could be scenarios where you may have two ophthalmologists and ten optometrists that may provide service in rural areas where a shortage of ophthalmologists and optometrists already exists.

Also we suggest that more than one ASC can be established by an applicant. This would allow potential economies of scale and potential help to increase access to surgical eye care.

We also make the suggestion that the language should state the ophthalmologist be 'board certified' and the optometrists must be credentialed to perform procedures in a surgical center. For example, to participate in an ASC one must be a board certified ophthalmologist, or a group of board certified ophthalmologists, or a group of Board certified Ophthalmologists and optometrists credentialed to perform procedures in a surgical center. We would also suggest the applicant group must contain a board certified ophthalmologist whom is a residency trained corneal specialist and a board certified ophthalmologist whom is a residency trained retina specialist. This addition of corneal specialist and retina specialist will greater improve access to this subspeciality care."

(b) Response: The cabinet appreciates the comments from Clarkson Eyecare. In light of all of the comments received and information reviewed from the federal Health and Human Services Office of Inspector General, the cabinet will delete the proposed changes to the SHP and retain the original language.

(a) Comment: Benjamin Mackey, M.D., John Franklin, M.D., and Ryan Smith, M.D., Kentucky Academy of Eye Physicians and Surgeons, submitted the following comments: "The Kentucky Academy of Eye Physicians & Surgeons is a statewide, non-profit professional association for ophthalmologists, trainees, technicians, and practice managers. As a collaborative society who partners with the American Academy of Ophthalmology, we have worked to improve provider education, access to care, and patient outcomes by organizing educational conferences, and advocating for patient safety and access to care by engaging various members of the treatment team including physicians, optometrists, patients, and other stakeholder groups for over 40 years.

Recent changes to the regulations, which would allow optometrist to co-own an ambulatory surgical center (ASC) with an ophthalmologist has raised several areas of major concern. Foremost, these changes could financially incentivize optometrists to refer patients to certain ophthalmologists. Also, this will potentially flood Medicaid and Medicare with claims for procedures performed at an ASC when the procedures are generally performed in-office and the billing is only for the provider fee. An ASC fee/claim could potentially double the cost (or more) for these procedures because a facility fee, in addition to the provider fee, will be added to the billing.

Specifically, this regulation change may conflict with Stark Laws (physician self-referral laws) and/or Federal Anti-kickback law. Stark laws are federal civil laws that prohibit physician self-referral, specifically a referral by a physician to an entity providing 'designated health services' (DHS) where the physician (or his/her immediate family member) has a financial relationship.

The federal Anti-Kickback Statute prohibits offering, paying, soliciting, or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid, and other federally funded programs. The Anti-Kickback Statute is intended to ensure that medical providers' judgments are not compromised by improper financial incentives and are instead based on the best interests of their patients.

The nature of the professional relationship between an optometrist and an ophthalmologist is one of patient referral. A large portion of these referrals are for cataract surgery (one of the most commonly performed surgeries in the United States). An optometrist is not professionally trained or legally able to perform cataract surgery, so they refer patients to an ophthalmologist to perform the surgery. The ophthalmologist gets paid a provider fee for doing the surgery and an ASC gets paid a facility fee for each cataract surgery that is performed.

This professional relationship can work well and there are established and accepted practices for co-managing patients between optometrists and ophthalmologists. In 2016, the American Academy of Ophthalmology updated its Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care. A principal aim of that revision was to better inform patients with full disclosure of compensation arrangements for the non-operating practitioner and fees that practitioners may charge beyond those that Medicare and other third-party payors would cover.

The AAO's Comprehensive Guidelines for the Co-Management of Ophthalmic Postoperative Care articulates that the surgeon is ultimately responsible for surgical management which begins with preoperative assessment and informed consent. A surgeon who delegates this function and who does not make an independent assessment of each patient does not meet these standards. Furthermore, 'routine' co-management that primarily serves the physician's or the optometrist's economic interest, rather than the patient's needs, raises both ethical and legal/regulatory concerns.

While care that does not require the unique competence of an ophthalmologist may be delegated, postoperative responsibility should not. Delegated services must be adequately supervised in all circumstances. The American College of Surgeons' statement on principles states that 'except in unusual circumstances, it is unethical for a surgeon to relinquish responsibility for the postoperative care to any other physician who is unqualified to provide similar surgical care.'

This regulation update also raises concern regarding fee splitting. The *Merriam Webster Dictionary* defines fee splitting as 'payment by a specialist (such as a doctor or a lawyer) of a part of his or her fee to the person who made the referral.' Although referral incentives are a common business practice in other industries, in medicine they erode the fiduciary relationship, potentially elevating a provider's financial interests above the needs of the patient.

The American Academy of Family Physicians defines fee-splitting as any division of fees without the full knowledge of the patient and with the intent of influencing the choice of physician, consultant, assistant, or treatment on any other basis than that of the greatest good of the patient.

In a co-management scenario, which may be common practice to a co-owned ASC with an optometrist and ophthalmologists, the patient pays the physician for the physician's services, and the patient pays any other provider such as an optometrist or physical therapist for those services. Co-management at its core is a series of referrals and stand-alone payment situations.

Fee splitting is not co-management; in fact, there is no circumstance where a physician should give payment directly to another provider. This is illegal and unethical. This may also become common practice in a co-owned ASC with an optometrist and ophthalmologists.

Fee splitting can be considered an inducement for referrals, which is an illegal act.

For instance, if co-management of cataract surgery with an optometrist is necessary due to the patient's circumstance, the patient will pay the surgeon for the surgery and the patient will pay the optometrist for their portion of post-surgical care. There is no need or justification for the optometrist to receive any payment for anything other than the care, such as any portion of the cost of a device or premium lens. This would be considered a referral inducement.

Due to these legal and ethical considerations, both parties are at risk when engaging in fee splitting and/or referral inducements. Referrals should be based on the needs of the patient alone.

This scenario resulted in a very public lawsuit in Texas where ophthalmology group K&E paid $2.9 million in remunerations for offering money to optometrists who referred patients to K&E for cataract surgery. The case in Texas should serve as a lesson on what Kentucky could experience when the co-management relationship becomes blurry which will definitively happen if optometrist are allowed to co-own an ASC.

There is also a case in Tennessee whereby a lawsuit was brought against Southeast Eye Specialists (SEES), which was owned equally by an ophthalmologist

and an optometrist. The case was initially filed by two physicians associated or previously associated with the TN Association of Optometric Physicians; however, after an independent investigation, the US Department of Justice and the State of Tennessee requested to join the suit. There was a lot of technical chaos that resulted in the US and State of TN's request to intervene, but it was clear that both the DOJ and State of TN found validity in the claim that Southeast Eye Specialists had violated the Anti-Kickback Statute. A good resource to learn more about this lawsuit can be found at United States v. Se. Eye Specialists, PLLC.pdf which should be a downloadable PDF of the lawsuit.

As of May 2nd, 2023, SouthEast Eye Specialists, SouthEast Eye Surgery Center and the Eye Surgery Center of Chattanooga (SEES) have agreed to pay the United States and Tennessee $17 million to resolve allegations that they violated federal anti-kickback statute.

In summary, we believe this change in state regulation is in direct violation of Stark law, could indirectly violate federal anti-kickback law and amounts to thinly veiled fee-splitting."

(b) Response: The cabinet appreciates the comments from the Kentucky Academy of Eye Physicians and Surgeons. In light of all of the comments received and information reviewed from the federal Health and Human Services Office of Inspector General, the cabinet will delete the proposed changes to the SHP and retain the original language.

(a) Comment: Donovan Blackburn, Pikeville Medical Center, submitted the following comments: "PMC also opposes changes in the SHP ambulatory surgery center ('ASC') criteria, which would allow an ASC jointly owned by ophthalmologists and optometrists to exemption from many ASC criteria under certain conditions. PMC believes that the proposed changes to the ASC review criteria for ASCs owned by Ophthalmologists in the SHP will greatly impact PMC's ability to continue to provide the critical specialty care that PMC currently provides to residents of Eastern Kentucky and will lead to an unnecessary proliferation of specialty ophthalmological/optometrist ASCs and costly duplication which will weaken PMC's ability to provide quality and efficient care. PMC further believes the changes should be deleted as not only contrary to the purposes of the Certificate of Need law and because these changes encourage and promote an ownership structure that is considered by the OIG to have the potential of violating the Anti-Kickback Law.

As you know, the SHP contains criteria that must be satisfied in order to obtain a certificate of need to establish or expand certain new health facilities or services. An 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 current SHP contains an exemption from many of these criteria for an ASC wholly owned by Ophthalmologists who are established in a community. The proposed change greatly expands this exemption. PMC opposes the proposed revision to the ASC criteria in the SHP for Ophthalmological ASCs for several reasons.

First, the proposed change to Section 5(c) allows an ASC to avoid many criteria if it is owned 50% by an Ophthalmologist and the remainder by an optometrist. Optometrists do not perform surgeries and should not be part of the exemption. Further the change to Section 5 (a) and (c) that changes the requirement that one owner have lived in the service area for five years rather than ten, means that an optometrist could partner with an ophthalmologist who does not even live in the service area to form an ASC. This would allow an outsider to come into a hospital's service area without ties to the ASC or to the community. This change would allow an ophthalmologist not practicing in the service area to join with a local optometrist to place an ASC in Pikeville and drain away valuable outpatient eye surgery revenue from its facility. PMC, like other rural regional referral hospitals 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. 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 we 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. The current state of hospitals must be taken into account when making the final decision on whether or not to make any SHP 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). Expanding the ASC ophthalmology exemption to allow optometrist ownership and no laser equipment investment to establish 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 ASCs 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.

Another problem with the change in criteria is that it encourages an ownership relationship that the OIG has recognized as has having the potential of violating the federal anti kickback law found at 42 U.S.C. Sec 1128B(1). The anti kickback statute makes it a criminal offense to knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referral of items or services reimbursable by a Federal health care program. In OIG Advisory Opinion No.07-13, the OIG concluded that including optometrists who do not perform surgery but who otherwise generated referrals, in ownership of an Ophthalmologist and Hospital owned ASC, did not satisfy the ASC safe harbor and the OIG could not conclude that the arrangement posed a minimal risk of fraud and abuse. See attached opinion. The proposed changes to the ASC criteria for ASCs limited to ophthalmological procedures encourages joint ophthalmologist/ optometrist ownership of these ASCs, and the potential of prohibited referrals under the Anti Kickback law which the OIG has found problematic. Accordingly, this language which not only allows but encourages joint ophthalmologists/optometrist ownership of an ASC should be struck.

In summary, ASC criteria changes like those proposed in the SHP 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, are unnecessary to accomplish legitimate goals, and encourage an ownership arrangement which the OIG has recognized poses a risk of violating the anti kickback law. Even if those arguments are ignored, the worst time to make the proposed changes is in the current post pandemic hardship period and its attendant economic slowdown."

(b) Response: The cabinet appreciates the comments from Pikeville Medical Center. In light of all of the comments received and information reviewed from the federal Health and Human Services Office of Inspector General, the cabinet will delete the proposed changes to the SHP and retain the original language.

(a) Comment: Russ Ranallo, Owensboro Health, Inc. (OHI), submitted the following comments: "OHI opposes the proposed amendment to expand the provision in the State Health Plan criteria for ambulatory surgery centers (ASCs) providing ophthalmic surgery procedures, to allow ownership by optometrists as well as ophthalmologists and reduce the pre-application period that they are required to provide services from ten years to five. This proposed change is not inconsequential as some might assume, but has real quality of care implications.

OHI has had experience with patients who live in its service area but have received ophthalmic surgeries (including surgeries in a facility across the river in Indiana),

coming to its emergency department with post-surgical complications. Unfortunately this often means that the surgeon who provided the care is not available to provide post-surgical care, either because that person does not live and practice in the area or because he or she chooses not to have hospital privileges. The absence of adequate follow-up care for ophthalmic surgeries sometimes leads to poor patient outcomes. The proposed rule would encourage the development of ASCs without assuring that appropriate follow-up care is available. This concern is not alleviated, and in fact would be exacerbated, by allowing optometrists (who cannot themselves perform surgical procedures) to participate in ownership of surgery centers, while only requiring one owner (not necessarily even an ophthalmologist) to have an office in the county. Nothing in the proposed change to the State Health Plan would promote access to quality health care. The only conceivable purpose for expanding the exception would be to allow optometrists to participate in the profit from surgeries based on referrals they make, which if anything suggests a potential for decreased patient freedom of choice and an increased risk of overutilization. There is no apparent health policy reason to carve out a special rule for optometrists.

While we oppose this change, if the Office of Health Policy feels strongly that optometrists should be able to participate in ophthalmic surgery centers, we suggest that the State Health Plan exception be specific that the at least one of the ophthalmologist owners must have a practice in the same county, and require that one or more ophthalmologist owners be available to provide post-surgical care, including response to emergencies."

(b) Response: The cabinet appreciates the comments from Owensboro Health, Inc. In light of all of the comments received and information reviewed from the federal Health and Human Services Office of Inspector General, the cabinet will delete the proposed changes to the SHP and retain the original language.

(4) Subject: Psychiatric Beds

(a) Comment: Donna Little, Kentucky Hospital Association (KHA), submitted the following comments: "In the State Health Plan section on Psychiatric Beds, a new Review Criteria 10 has been proposed to allow an existing licensed acute care hospital to establish up to twenty-five (25) psychiatric beds through acute bed conversion if the hospital is not located in a county with a freestanding psychiatric hospital and other requirements are met. Similar provisions are included in 900 KAR 6:075, Section 2(3)(h). KHA respectfully requests that the language in both locations be amended to limit the number of beds that can be converted to the lesser of twenty (20) percent of the facility's beds not to exceed twenty-five (25) beds. This will continue to provide flexibility to allow for the addition of psychiatric beds where needed to meet community needs while assuring that the bed conversion does not result in a hospital changing from an acute facility to a psychiatric hospital. This change was made in the Emergency Amended After Comments versions of the administrative regulations and we respectfully request the same changes for the ordinary versions."

(b) Response: The cabinet appreciates the comments from KHA and agrees with its recommendation. The cabinet will amend the language in the SHP accordingly.

(5) Subject: Hospice

(a) Comment: Brandy Cantor, Kentucky Association of Hospice and Palliative Care, submitted the following comments: "The members of the Kentucky Association of Hospice and Palliative Care (KAHPC) would like to submit this letter as comments regarding 900 KAR 5:020, the 2023 State Health Plan update. We welcome the opportunity to provide valuable insight about hospice care as we work to further improve health care outcomes for citizens of Kentucky. We want to thank the Cabinet for soliciting input from stakeholders, like KAHPC, who are advocates for quality care for people with life limiting illness. We believe that all eligible citizens should have access to the services hospice offers and we recognize the importance of assuring access to high quality health care for the citizens of the Commonwealth.

KAHPC members take access to hospice care very seriously and are dedicated to ensuring access to and providing the highest quality hospice care for Kentuckians with terminal illnesses. While KAHPC members feel the hospices across the state provide care at a level that enables every Kentuckian to receive superior quality hospice care at the end of life, they also understand the need to periodically evaluate the status of provider care and patients to ensure access to services. At this time, we believe that there is not evidence that patients who want hospice services are unable to find care or are being denied care by the existing hospice providers in the Commonwealth, regardless of their ability to pay.

KAHPC has engaged in multiple evaluations to review and analyze the current methodology, current statistics and need calculations. We've conducted an in-depth review of other state certificate of need laws, observed lessons learned from states without certificate of need, and examined unique factors affecting Kentucky. All to identify potential changes that could be made to increase access, use and quality of hospice in Kentucky.

Based on the outcomes of these efforts, it is clear the current hospice need methodology works well under normal circumstances. However, due to the COVID-19 pandemic, the past few years have been anything but normal for health care providers, hospice is no exception. As we emerge from the pandemic, KAHPC is assessing the impact and looking for solutions to prevent further disruptions to the delivery of high quality, patient centered hospice care to all Kentuckians who choose these services. KAHPC would recommend maintaining the current hospice need methodology, as it has become clear the COVID pandemic not only impacted how care was provided it has and will continue to skew the data used to project a need calculation. For these reasons, we request a temporary moratorium on new hospice providers to allow admission and death data to level out to a more normal range.

Our review of national death data seeks to understand what the impact for Kentucky might be and to ensure we are proactive in minimizing impact to patients. Typically, among Medicare beneficiaries, there is approximately a 40,000 death increase annually, however, from 2019- 2020 there was an increase of 400,000 deaths – 10 times the normal amount. We also know that hospice utilization typically increases by about 1.5% annually, but from 2019-2020 the use of hospice decreased nationally by just under 4% and from 2020-2021 utilization decreased nationally yet again by almost 2%. What this data tells us is that the pandemic had a very significant impact, and we are not free of that impact just yet. The significant increase in premature deaths during COVID will inevitably impact the number of patients eligible for hospice in the future. Many of those deaths were patients who died prematurely either from COVID or from lack of access to the medical care they needed to treat other diseases. Those patients, had they not died from COVID-19 or lack of medical care, would likely have been on a trajectory appropriate for hospice care in the future. But deaths, hastened by COVID, will now skew the number of potential patients eligible to enter hospice for some time and negatively impact hospice utilization.

As we know, Kentucky took a strong stance on restrictions and shutdowns to bend the curve and protect our citizens. These measures, while necessary, had an impact on hospice providers' ability to access patients and families. Hospice provides care in patients' homes, hospitals as well as nursing homes - all venues that became exceedingly difficult to access and provide care for patients during the pandemic. Hospice providers were often not allowed access to facilities, and patients were hesitant to have anyone in their home. These barriers have certainly impacted the utilization and penetration rates.

Since early 2020, The COVID-19 pandemic has had an undeniable impact on hospices throughout the United States and in Kentucky. The figure below shows the prevalence of COVID-19 among hospice patients in Kentucky, as measured by the percentage of Medicare revenue for patients with a diagnosis of COVID-19.

The impact of the pandemic on Kentucky hospices has been much more severe than in the rest of the country. There have been two seasonal winter peaks in COVID-19 prevalence. During the peak month of February 2022, the prevalence of COVID-19 hospice patients among Kentucky hospices (10.3 percent) was twice the national average (5.1 percent). Moreover, Kentucky ranked highest in COVID-19 prevalence among all the states.

The burden of high rates of COVID-19 among hospice patients was not shared equally among Kentucky's hospices. During the peak month of February 2022, two Kentucky hospices had COVID-19 rates at almost twice the level of the state average of 10.3 percent and four times the national average of 5.1 percent.

Kentucky hospice providers made necessary adjustments to service citizens during

COVID and while the Commonwealth saw a decline in utilization, it was not as significant as the decline nationally. This is a strong testament to the type of hospice providers we are blessed to have in Kentucky and the mission of those organizations.

As we have previously commented, KAHPC members support an evaluation to ensure access to hospice care is sufficient. However, members know the CON process is important for the hospice industry because of the nature of the business. While it is debatable that health care operates as a free market amongst other groups of providers, it is clear that hospice is not – hospice is a defined benefit with a fixed reimbursement. When price is fixed and supply is fixed the laws of supply and demand no longer apply. Market entry for providing hospice services is relatively easy as it can require minimal capital expenditures. Relaxing or eliminating the certificate of need program for hospice services would jeopardize the ability of the existing community based, not-for-profit programs in Kentucky to provide the highest quality of care to all patients regardless of ability to pay as they have for many years.

States with Hospice Certificate of Need regulations unanimously concur that an effectively implemented CON process results in strong protection of consumers, improved quality of care and supports the sustainability of existing providers. Both consumers and providers benefit from an effectively implemented CON process in several ways, including:

- An ongoing process to identify areas and populations with unmet health needs, paired with the ability to match providers to increase access to services meeting these needs – potentially increasing the access to timely, quality care.
- An adequate supply of providers with the expertise, financial resources, and commitment to meet the needs of their communities.
- An ongoing process that restricts unnecessary providers and services – potentially limiting the occurrence of fraud, waste, abuse, and the duplication of services that has been experienced in several states without CON, or after CON processes have been removed.

Some states have gone down the path of eliminating the certificate of need requirement and have seen firsthand the unintended consequences of this decision which include a proliferation of hospice programs, mostly for-profit organizations, generally located in highly populated urban areas that need them the least. Multiple case studies have shown that without CON, a proliferation of programs results with the greatest concentration in the metropolitan areas with the rural areas of the state rarely affected. This has resulted in lower quality service and higher rates of programs exceeding the hospice CAP which can be an indicator that patients are being inappropriately admitted to hospice in an effort to help the program survive with so many hospices in one area. None of these are desirable outcomes for Kentucky.

As an example, California recently imposed a moratorium on new hospice providers as a result of significant growth and fraud in the industry. As reported in the most recent MedPAC Report to Congress 2 , between 2019 and 2020, California gained 112 hospices, continuing the trend in recent years of substantial market entry by hospice providers in the state. From 2015 to 2020, California gained 110 hospices per year on average – almost exclusively for-profit hospices. As the OIG has increased scrutiny on the hospice industry, they identified California as one of the states with the most 'poor performers.' The hope for some with the new law is that the moratorium will help level the playing field for the nonprofit, community based, mission-driven hospices that have always put patients, families and the communities they serve first just as they do here in Kentucky.

The Medicare Payment Advisory Commission (MedPAC) has also researched and opined on the correlation between the number of hospices and access to care multiple times. Their findings state the number of hospice providers is not necessarily an indicator of beneficiary access to hospice. The supply of providers—as measured by the number of hospices per 10,000 Medicare decedents—varies substantially across states. In the past, we have concluded that no relationship exists between the supply of hospice providers and the rate of hospice use across states.[1]

Further they have stated the number of hospices in rural areas is not necessarily reflective of hospice access for rural beneficiaries for several reasons. A count of the number of rural hospices does not capture the size of those hospice providers, their capacity to serve patients, or the size of their service area. Furthermore, a count of rural hospices does not take into account hospices with offices in urban areas that also provide services in rural areas. While the number of rural hospices has declined in the last several years, the share of rural decedents using hospice grew through 2019. In addition, the number of rural beneficiaries receiving hospice services increased in 2020.[2]

Hospices in Kentucky are committed to providing access and quality services to every Kentuckian in need. In fact, hospice providers learned valuable lessons during the COVID pandemic that will increase access to hospice care. Specifically, the broader acceptance and use of telemedicine in hospice care has opened many valuable opportunities for outreach. There were many cooperative efforts between the state and providers that relaxed pre-pandemic rules or encouraged novel new ways of providing care. Best practices should become permanent because of the positive impact it has had on our providers' ability to increase access to quality hospice care. Providers are now raising awareness of hospice services by working alongside those who share a common interest in end-of-life care. Working within the newly created Palliative Care Interdisciplinary Advisory Council hospice organizations are helping create pathways for providing end of life care at the

[1]Medicare Payment Advisory Commission 2021, Medicare Payment Advisory Commission 2010
[2]MedPAC Report to the Congress: Medicare Payment Policy, March 2022

appropriate time, in the appropriate setting – all with the goal of increasing access. For example, in reviewing data, Kentucky hospice providers who also have a palliative care program are seeing increased numbers of African American patients choosing palliative care. What they are finding is that for this population palliative care seems to be a more acceptable form of care at the end of life and often once the disease has progressed those patients are more likely to then accept hospice. This is one example of how current providers are monitoring their programs and including changes to increase access and education among all demographics. Members of KAHPC are consistently reviewing their policies and practices to ensure access to care is being met.

As we look across the nation, the states we see having the most significant problems with inappropriate activity by hospice programs occurs in the states that do not have the protections of a CON program and have an abundance of for-profit hospice programs in the state. In 2009, Alabama re-enacted CON for hospice programs in order to control unnecessary proliferation of provider supply and the associated adverse consequences.

Kentucky hospice providers continue to focus on providing access and the highest quality of care to the citizens of Kentucky. At this time, we feel the current CON methodology for hospice is in line and is working to ensure access to care as well as high quality care from appropriate providers under normal circumstances. In fact, hospice penetration rates based on the Medicare claims from 2000-2013 show an overall statewide increase in penetration rates between 2000 and 2013.[1] Further, based on our analysis from 2018, hospice providers continue to meet the statewide need for Kentuckians. At this time, we are seeing no counties/areas within Kentucky that are significant outliers regarding availability hospice services.

In closing, as the hospice industry continues to grow across the nation, it is even more important to ensure that growth is appropriate and focused on delivering the highest quality of care to the patients served. The State of Kentucky has a hospice need methodology that is based on comparisons of local hospice performance with a 'typical' Kentucky area through the use of a median statistical measure. Under normal circumstances, the hospice certificate of need methodology is working to ensure proper growth and access to hospice services in the state. However, the COVID-10 pandemic completely undermines the notion of a typical area. Not only has Kentucky been disproportionately impacted by COVID-19 compared to other states, but there have also been widely divergent impacts within the state.

The Kentucky hospice need methodology combines three years of hospice and death data to smooth out normal variability in year-to-year deaths and market conditions. However, the impact of COVID-19 is not 'noise' but is an abrupt and systematic disruption and dislocation of mortality rates and health care markets. Under these circumstances, this need methodology cannot currently be relied upon to identify regions where the introduction of a new provider can be reasonably

[1]Kentucky State Summary of Medicare Hospice Utilization

expected to improve access to care over the long run. It will take time for the data to catch up and move back to a more 'normal' level making the methodology again reliable.

As we continue to emerge from the pandemic, now is not the time to make decisions that will change the delivery of care going forward. A moratorium will allow time for the data to level out and allow providers to continue to serve the citizens of Kentucky without limiting or jeopardizing access to care.

KAHPC continues to monitor and evaluate any opportunity to increase access to hospice care in appropriate manners that are in the best and balanced interest of patients and providers. KAHPC welcomes the opportunity to discuss this issue further if you desire. We appreciate your consideration of our thoughts and the work you do on behalf of the health care needs of our citizens."

(b) Response: The cabinet appreciates the comments from the Kentucky Association of Hospice and Palliative Care. The cabinet did not make any changes to the SHP plan related to hospice services.

(a) Comment: Liz Fowler, Bluegrass Care Navigators, submitted the following comments: "Hospice of the Bluegrass, Inc., dba Bluegrass Care Navigators (BCN) would like to submit this letter as comments regarding 900 KAR 5:020, the 2023 State Health Plan update. We welcome the opportunity to provide valuable insight about hospice care in the Commonwealth.

We are advocates for quality care for people with life limiting illness and believe that all eligible citizens should have access to the services hospice offers. We are dedicated to ensuring access and providing the highest quality hospice care to those with a terminal illness. Upon referral, BCN promptly admits any patient in our service area who is eligible for hospice services, regardless of their ability to pay.

The Kentucky hospice need methodology combines three years of hospice and death data to smooth out normal variability in year-to-year deaths and market conditions. However, the COVID-19 pandemic resulted in premature deaths of individuals who, if not for COVID-19, would have passed in a future year. The impact of premature deaths due to COVID-19, has decreased the number of individuals eligible for hospice care in future years. Therefore, we recommend no changes be made to the hospice need methodology at this time and a moratorium on new providers be put in place until the impact of COVID-19 deaths on the hospice need is fully understood. We anticipate a decrease in the number of patients eligible for hospice in the coming years and that current providers will be able to meet the demand for hospice services."

(b) Response: The cabinet appreciates the comments from Hospice of the Bluegrass. The cabinet did not make any changes to the SHP plan related to hospice services.

(a) Comment: David W. Cook, Hosparus, Inc. and Affiliates, submitted the following comments: "We appreciate the opportunity to comment on the 2023 State Health Plan. As a born and bred non-profit Kentucky hospice provider with nearly 44 years of experience in serving approximately 8300 patients throughout the Commonwealth each year, Hosparus Health, Inc. ('Hosparus') is honored to share our insight on the current and future status of hospice care. We thank you for considering our information and look forward to working with you in continuing to make Kentucky a model hospice state.

Who We Are

We practice Health Equity[1], in 28 different Kentucky counties, caring for patients of all backgrounds, races, ethnicities, ages (even children), religions, sexual orientation/identities, and disabilities – regardless of their ability to pay.

We give holistic care to each patient, not just the individual. Our services extend to the patient's family, caregivers, and other loved ones. We have countless volunteers, heroic care staff, and skilled grief counselors who care for the physical, mental, social, and spiritual aspects of patients and families facing a terminal illness, both before and after they choose hospice care – again, regardless of their ability to pay[2].

We serve with diversity. Our workforce is 89% female, 67% over the age of 40, 43% Black and African American certified nursing assistants, 16.16% minority direct caregivers, and 14% various declared racial backgrounds. We support our mission through an impressive 87% female member executive team (Chief Human Resources, Chief Medical Officer, Chief Legal Officer, Chief Development Officer, and Chief Nursing Officers).

We focus on serving minoritized communities. According to the 2019 US Census of Race/Ethnicity, 8.2% of Kentucky's state-wide population were minorities 65 years of age and older. Because Jefferson County is home to the largest sector of that population (18.1%), Hosparus focused on how to best reach and serve them. On July 1, 2022, Hosparus opened its new Resource Center in the YMCA to reach and serve West Louisville residents in the California, Russell, Parkland, and other surrounding neighborhoods.3 But we are not stopping there. In 2023, Hosparus will continue to expand its services and health equity strategic plan to minoritized communities and reach even more of Louisville and other underserved locations in the state.

We serve patients where they are, whether in their homes via personal and even telehealth visits, as well as in outpatient clinics, hospitals, assisted living facilities,

[1]https://www.cms.gov/files/document/health-equity-fact-sheet.pdf

and nursing homes.

We are reaching even more patients facing serious illness through our home-based palliative care program called Pallitus, which currently serves approximately 900 patients located throughout the Commonwealth who are not yet medically eligible for hospice or who avoid hospice care due to cultural differences and/or belief systems.

We are planning for the future of Kentucky hospice care through innovative and value-based care approaches, projects, and partnerships. Hosparus is currently in a Value Based Insurance Design model ("VBID") test program with Humana and will be joining an Accountable Care Organization in 2023, both of which embrace and explore provider reimbursement based on quality care and results, instead of the current fee for service model which CMS wants to retire. Hosparus also just opened an outpatient palliative care clinic in partnership with Baptist Hospital to better serve those needing such care and even more recently, was awarded a CON to open a PACE adult day care center in Elizabethtown, Kentucky, which is projected to open in early 2024 (pending CMS approval).

Who We Are Not

We are not a 'for-profit' organization and do not make decisions about care based on quarterly profit targets.

We are not 'new to the scene' of hospice care or Kentucky. We have been doing this for 44 years, right here in the Commonwealth where Hosparus was born.

How We See the Kentucky Hospice Industry

For-profits are looking to enter, and then gain a foothold here.

- Nationwide, for profit companies and private equity investors are entering the hospice industry at an alarming pace, and many of them without any previous hospice experience. Due to the headwinds of COVID, many smaller non-profit providers are being forced to 'sell out' as they cannot make ends meet.[1]
- Substantial gaps exist between for-profit and nonprofit margins in the hospice industry. Large national companies tend to have the larger double-digit margins, whereas the smaller nonprofits are often closer to that 3-to-5% range.[2] According to the Medicare Payment Advisory Commission, for-profit hospices had Medicare profit margins of 19%, compared with 6% for non-

[1] *Hospice News,* Jan. 19, 2022 by Jim Parker, "Nonprofit Hospices Selling to For-Profit Providers, Trend May Accelerate."

[2] *MedPAC,* March 2022 Report to Congress: Medicare Payment Policy; Chapter 11, Hospice Services, Page 334.

profit hospices.[1] By contrast, Hosparus currently sits at a negative profit margin through October 2022.

Industry data shows that not all hospice programs have the State's or Kentuckians' best interests at heart.

- "This year, in the wake of a Los Angeles Times investigation, California placed a moratorium on new hospices, and state auditors raised alarms about a raft of tiny new hospices, some with fictional patients and medical staff, that were engaged in a large-scale, targeted effort to defraud Medicare. In Los Angeles County alone, there are more than a thousand hospices, 99% of them for-profit. By comparison, Florida, which unlike California, requires new providers to prove a need for their services, has 51 hospices."[2]
- Medicare and Medicaid account for more than 90% of the revenue received for hospice services, which is a flat capitated rate. Profitability of hospice programs, therefore, is based completely on the cost of care provided. For-profit organizations target low-cost patients by location and diagnosis, cutting services and only caring for patients in urban areas where they can maximize utilization.[3] This is not Health Care equity.
- A recent 2021 article details what can happen when a state permits the over proliferation of for-profit hospice providers. California allowed a 1500% increase in the number of hospices there[4] and is suffering the consequences, including but not limited to a dramatic increase in poor care, poor quality, as well as billing and other fraud and large-scale abuses.[5]
- Kentucky employers, including State Agencies, all continue to suffer staffing and other woes from the COVID-19 pandemic. This means that Kentucky simply does not have the resources to monitor an influx of new providers, great or small, at this time.[6]

Kentucky's 2023 State Plan for Hospice Does Not Need Change.

- As the old saying goes, 'If it isn't broken, why fix it?' To date, Kentucky's CON process has been successful in making sure that its citizens' hospice needs are served adequately and with quality. In fact, Kentucky's current hospice providers soundly exceed the National Average in tracked quality measures, and Hosparus exceeds even the Kentucky average.[7]

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[1] *Kaiser Health News*, July 29, 2022 by Markian Hawryluk, "Patients for Profit: How Private Equity Hi-Jacked Healthcare – Hospices Have Become Big Business for Private Equity Firms, Raising Concerns About End-of-Life Care."

[2] http://www.propublica.org/article/hospice-healthcare-aseracare-medicare, Page 19, *emphasis added.*

[3] *See* FN 3 on previous page.

[4] To put this into perspective, as of 2019, Los Angeles alone had grown to 707 hospices, while the entire state of Florida only had 44. See FN 3 on previous page.

[5] *McKnight's Home Care,* Aug. 15, 2022 by Liza Berger, "What's Happening in California? Widespread Hospice Fraud Troubles Providers."

[6] *See* FN 3 on previous page, Detailing state Department of Public Health's inability to properly verify, investigate, and coordinate on the influx of new hospice agencies.

[7] https://www.medicare.gov/care-compare

- Kentucky currently has 24 different hospice providers, all of which are non-profits that provide care, regardless of the ability to pay, a notion for-profit providers do not embrace.

- Data shows that Kentucky's CON process has adequately ensured that the citizens of this Commonwealth get access to hospice and to quality hospice care which serves the whole person and family, again regardless of whether they can pay.

- Unlike current pending Kentucky CON hospice applicants, Hosparus voluntarily submits its care and performance for review and accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[1]

Current Kentucky Hospice Data Needs Updating and Clarification, Post COVID-19.

- We do not believe that Kentucky's CON process is perfect and should never change. Nor do we believe that nothing more should be done across the entire continuum of care, with all provider types, to further expand the public's understanding of hospice care and services and access to same, especially in the State's underserved areas and minoritized communities.
- But, when considering Kentucky's current state of hospice affairs, the State cannot forget that its hospice providers – like so many others – were significantly impacted by the COVID-19 pandemic. Hosparus was, and still is, no exception. Industry and other reports[2] show that fewer patients received hospice care nationwide specifically in 2022 due to:
    - Continued pandemic disruptions in referral streams
    - Workforce pressures / staff time off
    - Reduced clinical capacity
    - COVID-related hospice reorganizations, internal process, and leadership changes
- Unfortunately, the negative headwinds of the pandemic ultimately translated into disrupted and inaccessible hospice services for many Kentucky citizens, especially when the State essentially shut down as was needed, hospitals and nursing homes included. As COVID numbers increased, so did deaths across Kentucky of citizens who simply could not be served by hospice providers under pandemic circumstances.
- Equally important, to date and based on our best research efforts, Kentucky has not published any recent information on deaths by age, race, ethnicity, and other important categories. Excluding COVID deaths, the last published report on the State's website with this information is dated 2005. Information

[1] *See* Caris Healthcare September 2022 Hospice Kentucky CON application, noting it is not accredited by JCAHO and that it is a wholly owned subsidiary of a large for-profit nursing home chain. *See also MedPAC,* March 2022 Report to Congress: Medicare Payment Policy; Chapter 11, Hospice Services, Page 389, noting: "Hospices with a large share of patients in nursing facilities and assisted living facilities also have higher Medicare aggregate margins than other hospices."

[2] *See* FN 1, *MedPAC,* Pages 368-69.

from CMS and other federal agency sites fare no better.[1]

- This means that until such information is obtained, sorted out, and reviewed, we do not believe the State is adequately positioned to make a fully informed and educated decision about its hospice needs in the 2023 State Health Plan. The Plan, therefore, should remain 'as is.'
- Further, Governor Beshear's State of Emergency was rescinded in March 2022, only six months ago, and Kentucky's healthcare and hospice providers are still sifting through the COVID-19 pandemic rubble.
- Finally, the Biden Administration has yet to lift the federal Public Health Emergency COVID-19 declaration. In fact, roughly two weeks ago, the Biden Administration announced this will be extended into April 2023.[2]

In summary, we believe that Kentucky's hospice industry is strong and working to meet its citizens' needs, yet still fully awakening and reshaping itself from the world-wide pandemic that led to 17,459 deaths through November 21, 2022 in Kentucky alone. In addition, the current data being examined for the 2023 State Health Plan for Hospice is from year 2020, the first year of the pandemic, and we have yet to see what the data for pandemic years 2021 and 2022 will show. It is entirely too premature, therefore, for anyone to fully assess, much less apply, the resulting data and impacts the pandemic produced – some of which are still unknown. For these reasons, Hosparus respectfully submits that the State should place a moratorium on all pending and new CON activity as well as the 2023 State Health Plan for hospice.

Hosparus thrives on developing community partnerships that benefit the greater good of all Kentucky citizens who we have proudly cared for and served over the past 44 years. As a Kentucky born and bred business citizen, we look forward to continuing our mission of providing quality, holistic hospice care services and access to all for another 44 years, and we welcome the opportunity to work closely with the State and others in making sure this happens for every person in this Commonwealth needing hospice care."

(b) Response: The cabinet appreciates the comments from Hosparus, Inc. and Affiliates. The cabinet did not make any changes to the SHP plan related to hospice services.

(6) Subject: Pediatric Nursing Facilities

(a) Comment: Heidi Schissler Lanham, Kentucky Protection and Advocacy, submitted the following comments: "Kentucky Protection and Advocacy (P&A) is an independent state agency, federally created and federally funded, that provides

[1] See FN 1, *MedPAC*, Page 368-69, noting COVID-19 pandemic data limitations having only 2020 data and stating that "..significant uncertainty remains about the pandemic as well as the extent to which certain changes to hospice volume and financial performance will persist past the end of the PHE [public health emergency]...it will be more difficult to interpret these indicators than is typically the case."

[2] *Washington Examiner*, Nov. 11, 2022 by Abigail Adcox, "Biden to extend COVID-19 health emergency into April 2023: Report."

legally-based advocacy for persons with disabilities in Kentucky. Here are our comments regarding the above-referenced regulation and the 2023 Update to the State Health Plan.

On page 33 of the '2023 Update to the State Health Plan, March 2023' incorporated by reference to 900 KAR 5:020, in the section on Nursing Facility Beds, this proposed language appears:

> Notwithstanding criteria 1, 2, 3, and 4, an application to add fifty (50) or fewer beds shall be consistent with this Plan if submitted by a pediatric facility that is certified under Title XVIII and XIX of the Social Security Act and provides high intensity and low intensity nursing facility services to children, including residents who were admitted to the facility prior to age twenty-one (21) and remain in the facility after reaching the age of twenty-one (21).

There is currently only one pediatric facility in Kentucky to which this proposed language applies—Home of the Innocents Pediatric Convalescent Care (HOI PCC), a 76-bed dual licensed pediatric facility, in Louisville. HOI PCC patients must meet Nursing Facility (NF) Level of Care and may only be served there until the age of twenty-one.[1] All of the children and youth there 'face significant medical, developmental, and physical disabilities, many of whom require ventilator support.'[2] Depending on their medical and active treatment needs, when these youth age out of HOI PCC, they typically transfer to an institution— an Intermediate-Care Facility for Individuals with Intellectual Disabilities (ICF/IID) or an adult Nursing Facility, or into the community under one of the Medicaid 1915(c) waivers—Supports for Community Living (SCL), Michelle P., Home and Community Based Waiver (HCB), or Model II. The former two waivers require ICF/IID Level of Care while the latter two require NF Level of Care. Model II is the only waiver that covers nursing services.

Allowing HOI PCC to add adult NF beds elicits some concerns:

1. It's not the community—Title II of the Americans with Disabilities Act, as interpreted by the U.S. Supreme Court in Olmstead v. L.C.,[3] requires states to provide services to individuals with disabilities, including those aging out of HOI PCC, in the most integrated setting appropriate to their needs—usually the community.
2. It's a Nursing Facility without the Active Treatment and transition requirements of an ICF/IID. While individuals referred to a NF, including youth aging out of HOI PCC, must be provided a Pre-Admission Screening and Resident Review (PASRR) evaluation and Specialized Services if they meet certain criteria,[4] those services are not as robust as those required by an

[1] 907 KAR 1:032
[2] https://www.homeoftheinnocents.org/services/pediatric-convalescent-center/
[3] 527 U.S. 581 (1999)
[4] 42 USC 1396r; 907 KAR 1:755

ICF/IID.[1] In addition, unlike an NF, transition from an ICF/IID in Kentucky must be addressed upon admission.[2] Thus, an individual placed at the new HOI NF could remain there indefinitely.
3. It's costly—the average cost for the two state NFs, Western State Hospital NF and Glasgow State NF, is over $85,000. It is likely that the cost for the new HOI NF would be similar. That money could be better spent in the community.

While youth aging out of HOI PCC as well as their parents and caregivers could potentially choose the option of transferring to the new HOI NF, another answer is to add nursing services to the IDD waivers and/or for the Cabinet for Health and Family Services (CHFS) to develop a 'high intensity group home model [in the community] for adults with intellectual and developmental disabilities and complex medical needs' as recommended by the 2020 Exceptional Supports Task Force."

(b) Response: The cabinet appreciates the comments from Kentucky Protection and Advocacy. It is important to note that the changes to the SHP align with proposed changes to 907 KAR 1:025, filed by the Department for Medicaid Services on June 7, 2023, to permit residents of pediatric nursing facilities like HOI to continue residing there after turning 21 rather than be transferred to a geriatric or other facility. Because HOI's pediatric facility residents have significant medical, developmental, and physical disabilities, including many who require continuous ventilator support, the cabinet will retain the language of the SHP as written to avoid requiring transferring them to a facility that lacks the kind of social stimulation and intense care these young patients need.

(7) Subject: Intermediate Care Facility for Individuals with an Intellectual Disability (ICF/IID)

(a) Comment: Kara Daniel, Deputy Inspector General, Cabinet for Health & Family Services, provided the following comments:

In accordance with the 2023 passage of HB 334, an ICF/IID that is not a state-owned facility may increase its number of beds in accordance with the criteria established by the new law (KRS 216B.178). The cabinet will therefore amend the ICF/IID review criteria as follows:

An application for a new ICF/IID shall not be consistent with this Plan unless it is limited to a transfer of ICF/IID beds from an existing ICF/IID facility to the proposed ICF/IID facility. An application to increase the number of beds at an existing ***state-operated*** ICF/IID facility shall not be consistent with this Plan unless the increase in beds is accomplished by transferring beds from an existing ICF/IID facility.

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[1] 42 CFR 483.440

[2] https://www.justice.gov/sites/default/files/crt/legacy/2011/04/14/ocakwood_settlementagree 8-31-06.pdf pg. 12

(b) Response: The cabinet will amend the SHP via agency comment in accordance with the above changes.

Summary of Statement of Consideration and
Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation scheduled for May 22, 2023, was canceled. However, written comments were received during the public comment period. The Cabinet for Heath and Family Services, Office of Inspector General responded to the comments and amends the administrative regulation as follows:

Page 1
RELATES TO
Line 6
After "216B.010-216B.130", insert "**, 216B.178**".

Section 2
Line 19
After "Update to the State Health Plan",", insert "**July**".
Delete "March".

Material Incorporated by Reference
State Health Plan

Cover Page
Upper Right Corner
Edition Date
After "Date:", insert "**July**".
Delete "March".

Center of Page
Title
After "PLAN", insert "**July**".
Delete "March".

Table of Contents
Page ii
Delete all brackets and strikethroughs and restore existing page numbers.

Section II.A.10.b.ii.
Page 24
After "No more than", insert "**twenty (20) percent of the facility's**".
Delete "twenty-five (25)".
After "acute care beds", insert "**up to a maximum of twenty-five (25) beds**".

Section III.B.
Page 34
Review Criteria 4.
After "900 KAR 6:075, Section", insert "**2(3)(i)**".
Delete "2(3)(l)".

Section III.E.
Page 38
Review Criteria
After "number of beds at an existing", insert "**state-operated**".

Section IV.B.
Page 46
Delete the brackets and strike-throughs to restore all of the previously deleted language establishing the criteria for Megavoltage Radiation Equipment except for Review Criteria 1.b.
After "1.", delete "a.".
Page 47
Before "Positron Emission Tomography Equipment", restore "C."
Delete "B.".
Page 49
Before "New Technology", restore "D."
Delete "C.".

Section IV.E.
Page 51
Delete the brackets and strike-throughs to restore all of the previously deleted language establishing the criteria for magnetic resonance imaging equipment.

Section V.B.
Page 54
Review Criteria 5.a.
After "100% owned by ophthalmologists," delete the following language:
or an ophthalmologist-optometrist group, 100% owned by ophthalmologists and optometrists with at least one-half of the owners being ophthalmologists,
After "a period of", delete "at least five (5)".
Delete the brackets before and after "ten (10)" and delete the strike-through to restore the existing language.

Review Criteria 5.c.
After "c.", delete the brackets and strike-through to restore the existing language through "d.".

Review Criteria 5.d.
After "private office", delete the following language:
of at least one of the owners of the ASC

Renumber "d." as "e."
Renumber "e." as "f."