CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amended After Comments)

900 KAR 6:075. Certificate of need nonsubstantive review.

RELATES TO: KRS 216B.010, 216B.015, 216B.040, 216B.062, 216B.090, 216B.095, 216B.115, 216B.455, 216B.990

STATUTORY AUTHORITY: KRS 216B.040(2)(a)1., 216B.095

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1. requires the Cabinet for Health and Family Services to administer Kentucky's Certificate of Need Program and to promulgate administrative regulations as necessary for the program. KRS 216B.095 authorizes the review of certificate of need applications that are granted nonsubstantive status. This administrative regulation establishes the requirements necessary for consideration for nonsubstantive review of applications for the orderly administration of the Certificate of Need Program.

Section 1. Definitions.

(1) "Ambulatory surgical center" is defined by KRS 216B.015(4).

(2) "Cabinet" is defined by KRS 216B.015(6).

(3) "Certificate of Need Newsletter" means the monthly newsletter that is published by the cabinet regarding certificate of need matters and is available on the Certificate of Need Web site at https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx.

(4) "Days" means calendar days, unless otherwise specified.

(5) "Formal review" means the review of an application for certificate of need that is reviewed within ninety (90) days from the commencement of the review as provided by KRS 216B.062(1) and that is reviewed for compliance with the review criteria set forth at KRS 216B.040 and 900 KAR 6:070.

(6) "Nonsubstantive review" is defined by KRS 216B.015(18).

(7) "Public notice" means notice given through the cabinet's Certificate of Need Newsletter.

Section 2. Nonsubstantive Review.

(1) The cabinet shall grant nonsubstantive review status to an application to change the location of a proposed health facility or to relocate a licensed health facility only if:

(a) There is no substantial change in health services or bed capacity; and

(b)1. The change of location or relocation is within the same county; or

2. The change of location or relocation is for a psychiatric residential treatment facility.

(2) The cabinet shall grant nonsubstantive review status to an application that proposes to establish an ambulatory surgical center pursuant to the conditions specified in KRS 216B.095(7).

(3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant to KRS 216B.095(3)(f), the Office of Inspector General shall grant nonsubstantive review status to an application for which a certificate of need is required if:

(a) The proposal involves the establishment or expansion of a health facility or health service for which there is not a component in the State Health Plan;

(b) The proposal involves an application to re-establish a licensed healthcare facility or service that was provided at a hospital and was voluntarily discontinued by the applicant under the following circumstances:

1. The termination or voluntary closure of the hospital:

a. Was not the result of an order or directive by the cabinet, governmental agency, judicial body, or other regulatory authority;

b. Did not occur during or after an investigation by the cabinet, governmental agency, or other regulatory authority;

c. Did occur while the facility was in substantial compliance with applicable administrative regulations and was otherwise eligible for re-licensure; and

d. Was not an express condition of any subsequent certificate of need approval;

2. The application to re-establish the healthcare facility or service that was voluntarily discontinued is filed no more than one (1) year from the date the hospital last provided the service that the applicant is seeking to re-establish;

3. A proposed healthcare facility shall be located within the same county as the former healthcare facility and at a single location; and

4. The application shall not seek to re-establish any type of bed utilized in the care and treatment of patients for more than twenty-three (23) consecutive hours;

(c)1. The proposal involves an application to establish an ambulatory surgical center that does not charge its patients and does not seek or accept commercial insurance, Medicare, Medicaid, or other financial support from the federal government; and

2. The proposed ambulatory surgical center shall utilize the surgical facilities of an existing licensed ambulatory surgical center during times the host ambulatory surgical

center is not in operation;

(d) The proposal involves an application to establish an industrial ambulance service;

(e) Prior to July 1, 2026, the proposal involves an application by:

1. An ambulance service that is owned by a city or county government seeking to provide ambulance transport services pursuant to KRS 216B.020(9)(a)1. or 2.; or

2. A licensed hospital seeking to provide transport from a location that is not a health care facility pursuant to KRS 216B.020(9)(a)3. and (b);

(f) The proposal involves an application to transfer acute care beds from one (1) or more existing Kentucky-licensed hospitals to establish a new hospital under the following circumstances:

1. The existing hospital and new facility shall be under common ownership and located in the same county;

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

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

b. If the existing hospital is not a state university teaching hospital, the existing hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was three (3) stars or higher on the most recent annual update to the overall star ratings preceding the date the application was filed; [~~or~~]

(g)1. The proposal involves an application from a Program of All-Inclusive Care for the Elderly (PACE) program that:

a. Has met the requirements of the State Readiness Review (SRR) according to a report submitted by the Department for Medicaid Services (DMS) to the Centers for Medicare and Medicaid Services (CMS);

b. Seeks to provide, directly to its members, a health service that is not exempt from certificate of need (CON) under KRS 216B.020(1); and

c. Ensures that all services authorized under the PACE agreement are provided exclusively to its members who reside within the service area. The service area shall be:

(i) Located within the Commonwealth of Kentucky; and

(ii) Approved by both CMS and DMS.

2. Only an approved PACE program operating within the applicant's service area shall qualify as an affected person for the purpose of opposing a PACE program application.

3. A PACE program shall not be required to obtain certificate of need (CON) approval if the program:

a. Provides direct patient health services that are exempt from CON under KRS 216B.020(1) and provides other services subject to CON approval through contracts with licensed providers; or

b. Has already obtained CON approval within the approved PACE service area to provide a health service that is not exempt from CON;

(h) The proposal involves an application to establish an inpatient psychiatric unit in

an existing licensed acute care hospital under the following conditions:

1. The hospital is located in a county that has no existing, freestanding psychiatric hospital;

2. 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;

3. a. All of the proposed psychiatric beds are being converted from licensed acute care beds; and

b. No more than **twenty (20) percent of the facility's [~~twenty-five (25)~~]** acute care beds **up to a maximum of twenty-five (25) beds** will be converted to psychiatric beds;

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

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

(i) **[~~The proposal involves an application to provide megavoltage 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;~~**

~~(j) The proposal involves an application to provide positron emission tomography services;~~

~~(k) The proposal involves an application to provide magnetic resonance imaging services by an applicant that will be accredited by the American College of Radiology within twelve (12) months of licensure; or~~

~~(l)~~] The proposal involves 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 **who require home health services at the time of discharge [~~discharged~~]** from its facility.

(4) A certificate of need approved for an application submitted under subsection (3)(c) of this section shall state the limitations specified under subsection (3)(c)1. and 2. of this section.

(5) If an application is denied nonsubstantive review status by the Office of Inspector General, the application shall automatically be placed in the formal review process.

(6) If an application is granted nonsubstantive review status by the Office of Inspector General, notice of the decision to grant nonsubstantive review status shall be given to the applicant and all known affected persons.

(7)(a) If an application is granted nonsubstantive review status by the Office of Inspector General, any affected person who believes that the application is not entitled to nonsubstantive review status or who believes that the application should not be approved may request a hearing by filing a request for a hearing within ten (10) days of the notice of the decision to conduct nonsubstantive review.

(b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive review hearings.

(c)1. Except as provided in subparagraph 2. of this paragraph, nonsubstantive review applications shall not be comparatively reviewed.

2. If the capital expenditure proposed involves the establishment or expansion of a health facility or health service for which there is a component in the State Health Plan,

the nonsubstantive review applications shall be comparatively reviewed.

(d) Nonsubstantive review applications may be consolidated for hearing purposes.

(8) If an application for certificate of need is granted nonsubstantive review status by the Office of Inspector General, there shall be a presumption that the facility or service is needed and a presumption that the facility or service is consistent with the State Health Plan.

(9) If each applicable review criterion in the State Health Plan has been met, there shall be a presumption that the facility or service is needed unless the presumption of need has been rebutted by clear and convincing evidence by an affected party.

(10) Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of Inspector General shall approve each application for a certificate of need that has been granted nonsubstantive review status if the exception established in subsection (11)(a) of this section does not apply.

(11) The cabinet shall disapprove an application for a certificate of need that has been granted nonsubstantive review if the cabinet finds that the:

(a) Application is not entitled to nonsubstantive review status; or

(b) Presumption of need or presumption that the facility or service is consistent with the State Health Plan provided for in subsection (8) of this section has been rebutted by clear and convincing evidence by an affected party.

(12) In determining whether an application is consistent with the State Health Plan, the cabinet, in making a final decision on an application, shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the public notice of the application.

(13) In determining whether an application is consistent with the State Health Plan following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hearing that is held by virtue of a court ruling, the cabinet shall apply the latest criteria, inventories, and need analysis figures maintained by the cabinet and the version of the State Health Plan in effect at the time of the reconsideration decision or decision following a court ruling.

(14) A decision to approve or disapprove an application that has been granted nonsubstantive review status shall be rendered within thirty-five (35) days of the date that nonsubstantive review status has been granted, as required by KRS 216B.095(1). A hearing officer shall prioritize rendering decisions regarding applications granted nonsubstantive review status pursuant to Section 2(3)(g) of this administrative regulation.

(15) If a certificate of need is disapproved following nonsubstantive review, the applicant may:

(a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and 900 KAR 6:065;

(b) Request that the application be placed in the next cycle of the formal review process; or

(c) Seek judicial review pursuant to KRS 216B.115.

Section 3. Exemption from Certificate of Need.

(1) A city or county government-owned ambulance service that meets the criteria established by KRS 216B.020(8) shall not be required to obtain a certificate of need to provide emergency ambulance transport services.

(2) A hospital-owned ambulance service shall not be required to obtain a certificate of need to provide non-emergency or emergency transport that originates from its hospital pursuant to KRS 216B.020(7).

(3)(a) If a hospital-owned ambulance service has certificate of need approval prior to the most recent effective date of this administrative regulation to provide transport services from another health facility to its hospital, the service shall not be required to obtain authorization in accordance with paragraph (b) of this subsection.

(b) A hospital-owned ambulance service that is exempt from certificate of need under KRS 216B.020(7) may provide transport services from another health facility to its hospital if authorized as set out in KRS 311A.025(4).

(c)1. As used in paragraph (b) of this subsection, a hospital is authorized to provide inter-facility transport of a patient if:

a. The hospital contacts by phone at least one (1) ground ambulance provider with jurisdiction in the territory in which the other health facility is located, using contact information from the most recent edition of the agency directory maintained by the Kentucky Board of Emergency Medical Services at the following link (https://kbems.kctcs.edu/legal/EMS%20Directory.aspx); and

b. The ground ambulance provider:

(i) Declines the hospital's request for patient transport; or

(ii) Is not able to initiate the patient's transport within four (4) hours of receiving the hospital's request.

2. For purposes of this paragraph, a provider initiates transport when it arrives at the hospital to transport the patient.

3. The hospital shall document the ambulance service contacted and the reason for authorization to provide transport from another health facility to its hospital.

(4)(a) In accordance with KRS 216B.020(12)(a), the provisions of this section and Section 2(3)(e) of this administrative regulation shall expire on July 1, 2026.

(b) In accordance with KRS 216B.020(12)(b), a certificate of need exemption granted to an ambulance service under this section of this administrative regulation shall remain in effect on and after July 1, 2026.

900 KAR 6:075

REVIEWED:

7/12/2023
Date

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

APPROVED:

7/12/2023
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 6:075
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 establishes procedures for the nonsubstantive review of certificate of need applications. Nonsubstantive review is an expedited review process granted to certain applications pursuant to KRS 216B.095. This administrative regulation expands upon the types of applications that qualify for nonsubstantive review per the statute.

(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(18), 216B.040, and 216B.095.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by adding types of certificate of need applications that qualify for nonsubstantive review status, setting forth the procedure for granting nonsubstantive review status, and setting forth the procedure for affected parties to request a hearing to dispute the review status or application.

(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 adding types of certificate of need applications that qualify for nonsubstantive review status, setting forth the procedure for granting nonsubstantive review status, and setting forth the procedure for affected parties to request a hearing to dispute the review status or application.

(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: The originally proposed amendment added the following types of certificate of need applications to those that are granted nonsubstantive review status:

1. Applications by licensed hospitals to convert existing acute care beds to psychiatric beds for adult patients if certain criteria are met;
2. Applications by a licensed hospital to provide megavoltage radiation therapy;
3. Applications to provide positron emission tomography services;
4. Applications to provide magnetic resonance imaging services; and
5. Applications by a licensed acute care hospital, critical access hospital, or nursing facility proposing to establish or expand a home health service to serve patients discharged from its facility.

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

1. Amends the language of Section 2(3)(h) to change the maximum number of beds that may be converted from 25 beds to 20% of the facility's acute care beds, up to a maximum of 25 beds;

2. Deletes the proposal to grant nonsubstantive review to applications to provide magnetic resonance imaging services;

3. Deletes the proposal to grant nonsubstantive review to applications to provide positron emission tomography services;

4. Deletes the proposal to grant nonsubstantive review to applications to provide megavoltage radiation services; and

5. Cleans up the language of Section 2(3)(k) to match the language used in the State Health Plan.

(b) The necessity of the amendment to this administrative regulation: This amendment is being proposed pursuant to KRS 216B.095(3)(f), which permits the cabinet to grant nonsubstantive review status to a certificate of need application in accordance with circumstances prescribed by the cabinet via administrative regulation. These changes were requested by providers to allow them to add needed health care services more quickly and efficiently in response to their patient's changing needs. This amendment is needed to expand access to health services throughout the state, including in rural areas, to enhance immediate access to resources.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to KRS 216B.095(3)(f), which permits the cabinet to grant nonsubstantive review status to a certificate of need application in accordance with circumstances prescribed by the cabinet via administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by establishing the procedures for review of certificate of need applications granted nonsubstantive review status.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects entities that submit certificate of need applications subject to the nonsubstantive review process. The number of entities that submit certificate of need applications subject to nonsubstantive review varies.

(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: This amendment will permit nonsubstantive review of certificate of need applications for the applicants and healthcare services added in Section 2(3)(h) – (k) of this administrative regulation.

(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 is the same for nonsubstantive review and formal review and 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): The proposed amendment will help improve access to health care services by making it easier to obtain a certificate of need to provide these services. This will increase access to services that are closer to home for many patients, particularly in rural areas of the state.

(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? Tiering is used as certificate of need applications are reviewed under a formal review process (900 KAR 6:070) or nonsubstantive review process (this administrative regulation). The list of applications granted nonsubstantive review is being amended to add four (4) new categories.

FISCAL NOTE

Administrative Regulation: 900 KAR 6:075
Agency Contact: Kara Daniel
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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 affects entities that are subject to the certificate of need program's nonsubstantive review process. This administrative regulation also impacts the Cabinet for Health and Family Services, Office of Inspector General.

(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(8), 216B.040, 216B.095

(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 does 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 does 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.

STATEMENT OF CONSIDERATION
Relating to 900 KAR 6:075

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

I. The public hearing on 900 KAR 6:075, 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
Debbie Carroll Administrator	Professional Home Health Care Agency
Jeannie Cundiff Area Vice President of Operations	CenterWell Home Health
Liz Fowler President and CEO	Bluegrass Care Navigators
Stephanie Gettys, LNHA, CEAL Area Administrator	Interim HealthCare of Northern Kentucky
Ronald Herd, PE	Whitley County Board of Health
Donna Little Director of Health Policy and Regulatory Affairs	Kentucky Hospital Association

Donald H. Lloyd, II President/CEO	St. Claire Health Care
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
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. Please see the cabinet's response to the comments from St. Claire Health Care regarding additional changes to the SHP and 900 KAR 6:075 as well as upcoming changes to 900 KAR 6:080.

(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 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]

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

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 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 approximately 40 counties.[2] 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.

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[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.

[2] 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.

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-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 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 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

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

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 KHA. 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 re-instate 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: Psychiatric Beds

(a) Comment: Donna Little, Kentucky Hospital Association, 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 900 KAR 6:075 accordingly.

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 6
Section 2(3)(h)3.b.
Line 7
After "No more than", insert "**twenty (20) percent of the facility's**".
Delete "twenty-five".
Line 7
After "acute care beds", insert "**up to a maximum of twenty-five (25) beds**".

Section 2(3)(h)5.
Line 12
After "(64);", insert "**or**".

Section 2(3)(i)
Line 13
After "(i)", delete the following:

The proposal involves an application to provide megavoltage 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;
(j) The proposal involves an application to provide positron emission tomography services;
(k) The proposal involves an application to provide magnetic resonance imaging services by an applicant that will be accredited by the American College of Radiology within twelve (12) months of licensure; or
(l)

Page 6
Section 2(3)(l)
Line 23
After "exclusively patients", insert "**who require home health services at the time of discharge**".
Delete "discharged".