FILED WITH LRC
TIME: 1pm
AUG 14 2014
Donna Little
REGULATIONS COMPILER

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amended After Comments)

4 900 KAR 6:070. Certificate of need considerations for formal review.

5 RELATES TO: KRS 216B.010, 216B.090[~~216B.040~~], 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040[~~(2)(a)1.~~]

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
9 Program and to promulgate administrative regulations as necessary for the program.
10 KRS 216B.040(2)(a)2 requires the cabinet to promulgate an administrative regulation
11 establishing the criteria for issuance and denial of certificates of need. This administra-
12 tive regulation establishes the requirements necessary for the consideration for formal
13 review of applications for the orderly administration of the Certificate of Need Program.

14 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(6)[~~(5)~~].

15 (2) "Days" means calendar days, unless otherwise specified

16 (3) "Formal review" means the review of **an application**[~~**applications**~~] for certificate
17 of need which **is**[~~**are**~~] reviewed within ninety (90) days from the commencement of the
18 review as provided by KRS 216B.062(1) and which **is**[~~**are**~~] reviewed for compliance with
19 the review criteria set forth at KRS 216B.040 and in this administrative regulation.

20 (4) "Public information channels" means the Office of Communication and Adminis-
21 trative Review in the Cabinet for Health and Family Services.

1 (5) "Public notice" means notice given through:

2 (a) Public information channels; or

3 (b) The cabinet's Certificate of Need Newsletter.

4 Section 2. Considerations for Formal Review. In determining whether to approve or
5 deny a certificate of need, the cabinet's review of **an application**[~~applications~~] under
6 formal review shall be limited to the [~~following~~] considerations **established in this sec-**
7 **tion.**[~~:~~]

8 (1) Consistency with plans.

9 (a) To be approved, a proposal shall be consistent with the State Health Plan estab-
10 lished in 900 KAR 5:020.

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

15 (c) In determining whether an application is consistent with the State Health Plan fol-
16 lowing a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hear-
17 ing which is held by virtue of a court ruling, the cabinet shall apply the latest criteria, in-
18 ventories, and need analysis figures maintained by the cabinet and the version of the
19 State Health Plan in effect at the time of the reconsideration decision or decision follow-
20 ing a court ruling.

21 (d) An application seeking to re-establish a licensed healthcare facility or service that
22 was provided at the healthcare facility and which was voluntarily discontinued by the
23 applicant shall be considered consistent with the State Health Plan under the following

1 circumstances:

2 1. The termination or voluntary closure of the former healthcare service or facility:

3 a. Was not the result of an order or directive by the cabinet, governmental agency,

4 judicial body, or other regulatory authority;

5 b. Did not occur during or after an investigation by the cabinet, governmental agency,

6 or other regulatory authority;

7 c. Did occur while the facility was in substantial compliance with applicable adminis-

8 trative regulations and was otherwise eligible for relicensure;

9 d. Was not an express condition of any subsequent Certificate of Need approval; and

10 e. Did not occur less than twenty-four (24) months prior to the submission of the ap-

11 plication to re-establish;

12 2. The proposed healthcare service shall be provided within the same geographic

13 service area as the former healthcare service;

14 3. The proposed healthcare facility shall be located within the same county as the

15 former healthcare facility and at a single location; and

16 4. The application shall not seek to re-establish any type of bed utilized in the care

17 and treatment of patients for more than twenty-three (23) consecutive hours.

18 (2) Need. The cabinet shall determine:

19 (a) If the **applicant has identified a need for the [~~applicant's~~]** [~~applicant has iden-~~

20 ~~tified a need for the~~] proposal **in** **[~~for~~]** [~~in~~] the geographic service area defined in the ap-

21 plication**; and** **[~~is consistent with criteria, inventories, and need analysis figures~~**

22 **~~maintained by the cabinet and the State Health Plan, referenced in subsection (1)~~**

23 **~~of this section, and the applicant has demonstrated that it is able to meet the~~**

1 ~~need identified by the criteria, inventories, and need analysis maintained by the~~
2 ~~cabinet and the State Health Plan; or~~] [;~~and~~]
3 (b) [~~In the event the State Health Plan does not address the proposed health~~
4 ~~facility or service,~~] If the applicant has [~~identified a need for the proposal for the~~
5 ~~geographic service area defined in the application and has~~] demonstrated that it is
6 able to meet the need identified **in the geographic service area defined in the appli-**
7 **cation** [~~in the geographic service area defined in the application~~].
8 (3) Accessibility. The cabinet shall determine if the health facility or health service
9 proposed in the application will be accessible in terms of timeliness, amount, duration,
10 and personnel sufficient to provide the services proposed.
11 (4) Interrelationships and linkages. The cabinet shall determine:
12 (a) If the proposal shall serve to accomplish appropriate and effective linkages with
13 other services, facilities, and elements of the health care system in the region and state;
14 and
15 (b) If the proposal is accompanied by assurance of effort to achieve comprehensive
16 care, proper utilization of services, and efficient functioning of the health care system.
17 (5) Costs, economic feasibility, and resource availability. The cabinet shall determine:
18 (a) If it is economically feasible for the applicant to implement and operate the pro-
19 posal; and
20 (b) If applicable, if the cost of alternative ways of meeting the need identified in the
21 geographic area defined in the application would be a more effective and economical
22 use of resources.
23 (6) Quality of services.

1 (a) The cabinet shall determine if the applicant:

2 1. Is prepared to, and capable of undertaking and carrying out, the responsibilities in-
3 volved in the proposal in a manner consistent with appropriate standards and require-
4 ments established by the cabinet; and

5 2. Has the ability to comply with applicable licensure requirements.

6 (b) Absence of an applicable licensure category shall not constitute grounds for dis-
7 approving an application.

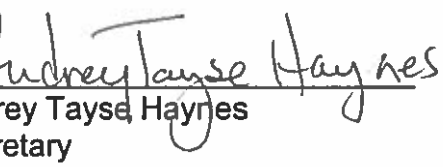
900 KAR 6:070

REVIEWED:

Emily Whelan Parento
Executive Director
Office of Health Policy

7/31/14
Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services

8/7/14
Date

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Regulation: 900 KAR 6:070
Contact Person: Diona Mullins,
Office of Health Policy
(502) 564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the guidelines for formal review of certificate of need applications.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.040(2)(a)1.

(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 establishing the requirements necessary for consideration of certificate of need applications undergoing formal review.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements necessary for consideration of certificate of need applications undergoing formal review.

(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 regulation is changed to clarify that in determining whether an application is consistent with the State Health Plan, 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 public notice of the application. When making a final decision following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration hearing which is held by virtue of a court ruling , 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 shall be applied by the Cabinet. The Amended After Comments administrative regulation restores the original language of Section 2(2) Need.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to clarify which documents will be relied upon in making certificate of need decisions regarding consistency with the State Health Plan. The Amended After Comments administrative regulation restores the original language of Section 2(2).

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation establishes requirements necessary for consideration for formal review of certificate of need applications.

(d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes requirements necessary for consideration for formal review of certificate of need applications.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file a formal review certificate of need application. Annually, approximately 150 certificate of need applications are filed.

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

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: A certificate of need application requesting formal review will be required to meet the requirements of this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional cost to entities to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants will know the certificate of need application requirements for formal review.

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

(a) Initially: No cost

(b) On a continuing basis: No cost

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing 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.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation: 900 KAR 6:070
Contact Person: Diona Mullins, Policy Advisor, 502-564-9592

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? Health care facilities owned by the state, county or city which submit certificate of need applications requesting formal review will be impacted by this regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1 and KRS 216B.040(2)(a)2.

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

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

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

(c) How much will it cost to administer this program for the first year? No additional costs are necessary to administer this program during the first year

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to administer this program for 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

STATEMENT OF CONSIDERATION RELATING TO
900 KAR 6:070
Office of Health Policy

Amended After Comments

(1) The public hearing on 900 KAR 6:070, scheduled for June 23, 2014 at 9:00 a.m. in the Health Services Building was cancelled; however written comments were received during the public comment period.

(2) The following individuals submitted written comments via the public comment process:

NAME AND TITLE	AGENCY/ORGANIZATION/ENTITY/OTHER
Michael T. Rust President	Kentucky Hospital Association Louisville, KY
Michael D. Baker	Wyatt, Tarrant & Combs, LLP Lexington, KY
Chip Peal CEO	Frankfort Regional Medical Center Frankfort, KY
Russ Ranallo VP Financial Services	Owensboro Health Regional Hospital Owensboro, KY
John S. Dubis President and CEO	St. Elizabeth Healthcare Edgewood, KY
Joseph G. Koch CEO	Bourbon Community Hospital Paris, KY
Erika Skula President/CEO	Manchester Memorial Hospital Manchester, KY
Wade R. Stone Exec. Vice President	The Medical Center Bowling Green, KY
Don Borraga Area Director, Operations	VNA Nazareth Home Care Louisville, KY

Vicki A. Darnell President & CEO	Ephraim McDowell Health, Inc. Danville, KY
Carl Metz Vice President	Ephraim McDowell Health, Inc Danville, KY
William M. Snapp Vice President & CFO	Ephraim McDowell Health, Inc Danville, KY
Megan Shelton Clinical Manager Behavioral Health Services	Ephraim McDowell Health, Inc Danville, KY
Christy Mullins Director-Behavioral Health Services	Ephraim McDowell Health, Inc Danville, KY
Michael Jackson Vice President	Ephraim McDowell Health, Inc Danville, KY
Ina Pless Vice President	Ephraim McDowell Health, Inc Danville, KY
Robert Parker CEO	Meadowview Regional Medical Center Maysville, KY
David D. Anderson CEO	Jackson Purchase Medical Center Mayfield, KY
Colleen McKinley	Memorial Hospital Manchester, KY
Janet Craig	Pikeville Medical Center, Inc. Pikeville, KY
Tim Trottier CEO	Spring View Hospital Lebanon, KY
Randall S. Strause	Maxim Healthcare Services
Denis Fleming, Jr. VP of Government Services	Almost Family
Joseph L. Grossman President & CEO	Appalachian Regional Healthcare, Inc. Lexington, KY

Marie Alagia Cull	Kentucky Home Care Association Lexington, KY
Mark J. Neff President/CEO	St. Claire Regional Medical Center Morehead, KY
Jeannie Cundiff Area VP of Operations	Gentiva Health Services
Andy Sears Chief Strategy and Marketing Officer	Baptist Health Louisville, KY
Emily Whelan Parento Executive Director	Office of Health Policy Frankfort, KY

(3) The following individuals from the promulgating administrative body responded to the comments received:

NAME AND TITLE	AGENCY/ORGANIZATION/ENTITY/OTHER
Emily Whelan Parento Executive Director	Office of Health Policy
Diona Mullins Policy Advisor	Office of Health Policy

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Statutory Mandate for Distinct Criteria for Consistency with Plans and Need and Accessibility

(a) Comment: Michael T. Rust, Kentucky Hospital Association; Chip Peal, Frankfort Regional Medical Center; Russ Ranallo, Owensboro Health Regional Hospital; John S. Dubis, St. Elizabeth Healthcare; Joseph G. Koch, Bourbon General Hospital; Erika Skula, Manchester Memorial Hospital; Wade R. Stone, The Medical Center; Don Borraga, VNA Nazareth Home Care; Vicki A. Darnell, Carl E. Metz, William A. Snapp, Megan Shelton, Christy Mullins, Michael Jackson, and Ina Pless, Ephraim McDowell Health, Inc.; Robert Parker, Meadowview Regional Medical Center; David D. Anderson, Jackson Purchase Medical Center; Janet Craig, Pikeville Medical Center, Inc, Tim Trottier, Spring View Hospital; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; Marie Alagia Cull, Kentucky Home Health Association; Mark J. Neff, St. Claire Regional Medical Center; Jeannie Cundiff, Gentiva Health Services; and Andy Sears, Baptist Health provided comments consistent with the following comments provided by Michael D. Baker, Wyatt, Tarrant & Combs, LLP:

"KRS 216B. 040(2)(a)2. provides that the Cabinet 'shall' promulgate regulations establishing the criteria for reviewing CON applications, which criteria 'shall' be limited to those set out in the statute. It proceeds to list those, including 'a. Consistency with plans,' providing that for a proposal to be approved it 'shall' be consistent with the State Health Plan. The statute proceeds to set out a separate and distinct mandatory "need criterion: 'b. Need and accessibility. The proposal shall meet an identified need in a defined geographic area and be accessible to all residents of the area. A defined geographic area shall be defined as the area the proposal seeks to serve, including its demographics, and shall not be limited to geographical boundaries.'

These are listed separately in the statute for a reason. If the legislature had intended for 'consistency with plans' and 'need' to be one and the same, it would have included them in the same criterion. Indeed , the language concerning the defined geographic area clearly demonstrates one of the differences in these criteria. For purposes of consistency with the State Health Plan, each service has a clearly defined geographic area, which is limited to geographic boundaries. Some of those are the county, some are the county and contiguous counties, others are the area development district, etc. However, for the distinct purpose of proving, or disproving, 'need' under Criterion Two, the geographic area at issue can be smaller than that provided for in the State Health Plan, or it can be larger.

In any event, the statute expressly requires that these be separate and distinct criteria. The Cabinet should not be regulation attempt, as a practical matter, to merge them into one."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Comment: Michael D. Baker, Wyatt, Tarrant & Combs, LLP; Chip Peal, Frankfort Regional Medical Center; Russ Ranallo, Owensboro Health Regional Hospital; John S. Dubis, St. Elizabeth Healthcare; Joseph G. Koch, Bourbon General Hospital; Erika Skula, Manchester Memorial Hospital; Wade R. Stone, The Medical Center; Don Borraga, VNA Nazareth Home Care; Vicki A. Darnell, Carl E. Metz, William A. Snapp, Megan Shelton, Christy Mullins, Michael Jackson, and Ina Pless, Ephraim McDowell Health, Inc.; Robert Parker, Meadowview Regional Medical Center; David D. Anderson, Jackson Purchase Medical Center; Janet Craig, Pikeville Medical Center, Inc, Tim Trottier, Spring View Hospital; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; Marie Alagia Cull, Kentucky Home Health Association; Mark J. Neff, St. Claire Regional Medical Center; Jeannie Cundiff, Gentiva

Health Services; and Andy Sears, Baptist Health provided comments consistent with the following comments provided by Michael T. Rust, Kentucky Hospital Association:

"The proposed language ignores the fact that the statute defines separately and describes each criterion. Consistency with the State Health Plan and Need and Accessibility criteria are separate in the statue, regulation and application forms. The two criteria have always been independent considerations during the hearing process as well as in written decisions issued by the Division of Administrative Hearings, the Franklin Circuit Court and the Kentucky Court of Appeals when ruling on Certificate of Need appeals. This distinction not only complies with Kentucky law but also recognizes that the State Health Plan methodology does not incorporate innumerable factors relevant to "need" which must be considered in the review of new health facilities and services.

Altering a regulation in this way directly contravenes KRS Chapter 13A and years of legal precedent in Kentucky. A regulation cannot exceed the authority granted by its enabling statute. Specifically, KRS 13A.200 and KRS 13A.120 address the limited power of an administrative agency such as the Cabinet for Health and Family Services when promulgating regulations. Exceeding statutory authority or rewriting the clear mandate of the statute are expressly prohibited. The Cabinet's above-cited language eradicates CON Applicant's statutory mandate to prove a need for their proposal separate and apart from the State Health Plan. Such action is illegal, unconstitutional and should not be pursued.

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Michael D. Baker, Wyatt, Tarrant & Combs LLP; Chip Peal, Frankfort Regional Medical Center; Russ Ranallo, Owensboro Health Regional Hospital; John S. Dubis, St. Elizabeth Healthcare; Joseph G. Koch, Bourbon General Hospital; Erika Skula, Manchester Memorial Hospital; Wade R. Stone, The Medical Center; Don Borraga, VNA Nazareth Home Care; Vicki A. Darnell, Carl E. Metz, William A. Snapp, Megan Shelton, Christy Mullins, Michael Jackson and Ina Pless, Ephraim McDowell Health, Inc.; Robert Parker, Meadowview Regional Medical Center; David D. Anderson, Jackson Purchase Medical Center; Janet Craig, Pikeville Medical Center, Inc, Tim Trottier, Spring View Hospital; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; Marie Alagia Cull, Kentucky Home Health Association; Mark J. Neff, St. Claire Regional Medical Center; Jeannie Cundiff, Gentiva Health Services; and Andy Sears, Baptist Health provided comments consistent with the following comments provided by Michael T. Rust, Kentucky Hospital Association regarding Sect. 2(2)(a):

"...The State Health Plan does not (and cannot by virtue of the quickly changing health care delivery and payment systems) always reflect up-to-date criteria and current utilization because the criteria are not always updated regularly to reflect the current health care environment. State Health Plan criteria does not reflect other contributing factors to overall need for services such as health care delivery system changes and the impact of changes in payment systems (e.g. The implementation of Medicaid managed care). Kentucky law KRS 216B.040 established five criteria to ensure that a broad and thorough approach is used in the review process when determining if a service of facility is needed.

In addition to the established criteria within the State Health Plan, the CON review process requires, through statute, the consideration of other evidence and information that is more timely and reflective of the current health care environment. The 'need' criteria is likely the most significant of these criteria as it requires applicants to evaluate the need of the population to be served given the most recent available information. The most recent changes in utilization in Kentucky as a result of implementation of Medicaid managed care is the best example as to how important it is to retain this element of evaluation in the CON program. Since November 2012, utilization for certain services has sharply declined. State Health Plan criteria do not reflect this information or that excess capacity exists and reference documents like the Utilization and Services Reports referenced in the State Health Plan lag behind by 12 to 24 months. If need was to be determined based on the criteria and these published reports alone, an applicant could be found consistent with need when in fact there is significant excess capacity in a given planning area."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Comment: Michael T. Rust, Kentucky Hospital Association; Michael D. Baker, Wyatt, Tarrant & Combs LLP; Russ Ranallo, Owensboro Health Regional Hospital; Don Borraga, VNA Nazareth Home Care; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; and Jeannie Cundiff, Gentiva Health Services; provided comments consistent with the following comments provided by Marie Alagia Cull on behalf of the Kentucky Home Care Association:

"Additionally from a health policy and health planning perspective, the Cabinet's proposed language is based on multiple faulty assumptions. First, the State Health Plan methodology only considers data that are limited to age, population, and average statewide utilization rates. While instructive for certain purposes, application of a statewide utilization rate to a county is not indicative of 'need.' Various other factors

including, but not limited to, health status, poverty rates, access to other levels of health care, and individual physician practice patterns significantly impact the potential need for additional health care services in a particular area. Need varies significantly across the Commonwealth as do the demographics directly linked to health status and home health utilization. Further, the data clearly shows that there is absolutely no correlation between the number of licensed home health agencies in a county and that county's utilization rate. Therefore, increasing the number of licensed agencies in any particular county will not necessarily increase overall utilization – there is no relationship between low utilization and a small number of licensed agencies or multiple agencies and a higher overall use rate for home health. ...

Historically, when CON is relaxed or lifted, states quickly experience dramatic growth in the number of agencies; such growth inevitably leads to multiple issues including, but not limited to, CMS and OIG inquiries. There are undesirable results for the Commonwealth and its residents."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Vicki A. Darnell, Carl E. Metz, William A. Snapp, Megan Shelton, Christy Mullins, Michael Jackson and Ina Pless, Ephraim McDowell Health, Inc. provided the following comment:

"The Cabinet's existing methodology for Psychiatric services within the State Health Plan shows a higher need for inpatient beds than is actually needed given that Medicaid Managed Care Organizations have reduced utilization of inpatient beds by 40%. Therefore, if an applicant is not required to demonstrate need for beds, the proposed regulation would allow for the addition of beds for inpatient psychiatric services where excess capacity already exists."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Comment: Michael T. Rust, Kentucky Hospital Association; Chip Peal, Frankfort Regional Medical Center; Russ Ranallo, Owensboro Health Regional Hospital; John S. Dubis, St. Elizabeth Healthcare; Joseph G. Koch, Bourbon General Hospital; Erika

Skula, Manchester Memorial Hospital; Wade R. Stone, The Medical Center; Don Borraga, VNA Nazareth Home Care; Vicki A. Darnell, Carl E. Metz, William A. Snapp, Megan Shelton, Christy Mullins, Michael Jackson, and Ina Pless, Ephraim McDowell Health, Inc.; Robert Parker, Meadowview Regional Medical Center; David D. Anderson, Jackson Purchase Medical Center; Janet Craig, Pikeville Medical Center, Inc, Tim Trottier, Spring View Hospital; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; Marie Alagia Cull, Kentucky Home Health Association; Mark J. Neff, St. Claire Regional Medical Center; and Jeannie Cundiff, Gentiva Health Services provided comments consistent with the following comments provided by Michael D. Baker, Wyatt, Tarrant & Combs, LLP:

"KRS 216B. 085 gives 'affected persons' a statutory right to a hearing on applications for a certificate of need. However, the proposed amendment ... appears to relieve applicants from their statutory duty of providing 'need.' It also appears to preclude affected parties from even introducing evidence concerning the lack of need in cases where an application is consistent with the State Health Plan. As a practical matter, this reduces or eliminates the statutory right to a hearing on formal review applications."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(a) Comment: John S. Dubis, President and CEO, St. Elizabeth Healthcare, provided the following comment:

"...The Need Criteria requires the applicant to show that the proposed healthcare service or facility 'will be accessible to all residents of the area.' Removing this requirement will permit healthcare providers to enter the Kentucky marketplace that do not serve Medicaid recipients and the uninsured."

(b) Response: The Cabinet's decision to file the regulation amendment was an attempt to rectify situations where the "need" methodologies in the State Health Plan, which are developed with input from providers, are not given due weight when determining if an application is consistent with the need criterion described in KRS 216B.040. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(2) Subject: Ambiguous Language in Section 2(2)(a) and (b)

(a) Comment: Russ Ranallo, Owensboro Health Regional Hospital; Don Borraga, VNA

Nazareth Home Care; Denis Fleming, Jr., Almost Family; Joseph L. Grossman, Appalachian Regional Healthcare, Inc.; and Jeannie Cundiff, Gentiva Health Services provided comments consistent with the following comments provided by Michael D. Baker, Wyatt, Tarrant & Combs, LLP:

"It isn't clear exactly what is meant by the language in the proposed amendment, especially the interplay between Section 2(2)(a) and 2(2)(b). On its face, (a) appears to apply to cases where a project is addressed in the State Health Plan. On the other hand, (b) expressly applies where 'the State Health Plan does not address the proposed health facility or service.' However, if the State Health Plan does not address the facility or service, in most if not all cases, either a CON would not be required or the application would qualify for nonsubstantive review status and would not be reviewed under formal review."

(b) Response: After consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(3) Subject: Support of Amendment

(a) Colleen McKinley on behalf of Memorial Hospital, Manchester, KY provided the following comment in support of the proposed amendment:

"...We believe the amendment improves considerably the regulation's conformity with the statute that deals with the same subject."

(b) Response: The Cabinet acknowledges this comment in support of the proposed amendment. However, after consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(4) Recommended Revision to Need Criterion

(a) Randall S. Strause, on behalf of Maxim Healthcare Services, Inc. provided the following comments:

"Affected parties have capitalized upon the rather vague and ambiguous wording of the need criterion and essentially used it as a moving target to successfully convince hearing officers that no 'need' exists because applicants failed to satisfy their arbitrary benchmarks. ...We believe the intent of the proposed amendment is to clarify the need criterion and eliminate monopolies in certain health services 'to improve the quality and increase access to health-care facilities, services, and providers, and to create a cost-efficient health-care delivery system for citizens in the Commonwealth.' ...We respectfully submit that the proposed amendment is still ambiguous, subject to multiple interpretations, and inapplicable in some regards to home health and private duty nursing services. For example, unlike home health and several other health services, need analysis figures are not maintained for private duty nursing services; thus, the

need analysis figures component would be inapplicable to review of private duty nursing proposals. In regard to home health, inventories are not directly considered for purposes of determining whether an applicant's proposal is consistent with the State Health Plan. It is difficult to conceive how a home health applicant's proposal could demonstrate consistency with inventories because almost all, if not every geographic service area is already served by one or more agencies. It would be quite easy for affected parties to argue that home health applicants would never be consistent with 'inventories' as long as at least one agency is operating within the geographic service area and willing to service additional patients. Finally, the term 'consistent with criteria' could be interpreted to mean criteria separate from the State Health Plan criteria for the various health services. This ambiguity could give affected parties the opportunity to advance their own arbitrary criteria not intended under this regulation. ...

We respectfully submit that the recommended revisions would more effectively achieve the Office of Health Policy's objectives, satisfy the intent of the Certificate of Need process, eliminate ambiguity, and provide objective criteria for applicants and reviewing hearing officers:

(2) Need. The cabinet shall determine:

(a) If the applicant's proposal for the geographic service area defined in the application is consistent with the State Health Plan, referenced in subsection 1 of this section, and the applicant has demonstrated that it is able to meet the need identified by the State Health Plan criteria; or

(b) In the event the State Health Plan does not address the proposed health facility or service, the applicant has identified a need for the proposal for the geographic service area defined in the application and has demonstrated that it is able to meet the need identified.

This revision eliminates the ambiguity and potential inapplicability that reference to criteria, inventory, and need analysis figures creates. Moreover, it reestablishes that the State Health Plan methodology prevails regarding determinations of whether a need exists in the geographic service area. While some may argue that applicants would have the benefit of the State Health Plan indicated need to satisfy two criteria that would not be the case. Applicants would still be require to demonstrate that they understand what the unmet need is in the geographic service area and have the ability to provide the service lines that are needed.

Alternatively, we would propose the following language:

(a) If the applicant's proposal for the geographic service area defined in the application seeks to address an unmet need for services identified by the State Health Plan, utilization service reports, inventories, need analysis figures, or the geographic service area's community, and the applicant has demonstrated that it is able to meet the need identified by the State Health Plan criteria; or

(b) In the event the State Health Plan does not address the proposed health facility or service, the applicant has identified a need for the proposal for the geographic service area defined in the application and has demonstrated that it is able to meet the need identified. "

(b) Response: After consideration of the comments received during the public comment period, the Cabinet will amend the regulation to retain the original language in Section 2(2) regarding the need criterion.

(5) Subject: Drafting and Formatting Changes

(a) Comment: Agency staff determined that a number of drafting and formatting changes were needed to comply with KRS Chapter 13A by correcting section numbering, changing plural to singular, and clarifying intent.

(b) Response: Drafting and formatting changes will be made as needed.

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

The Office of Health Policy (OHP) has considered the comments received regarding 900 KAR 6:070 and is amending the administrative regulation as follows:

Page 1
TITLE
Lower case "Need"

Page 1
Section 1(3)
Line 17
After "review of", insert "an application".
Delete "applications".
Lines 17 and 18
After "which", insert "is".
Delete "are".
Line 19
After "and which", insert "is".
Delete "are".

Page 2
Section 2
Line 6
After "review of", insert "an application".
Delete "applications".

Line 7

After "limited to the", delete "following".
After "considerations", insert "established in this section.".
Delete the colon.

Page 3
Section 2(2)(a)
Line 20

After "If the", insert the following:
applicant has identified a need for the
Delete "applicant's".
After "proposal", insert "in".
Delete "for".

Pages 3 and 4
Section 2(2)(a)
Lines 21 to 23, 1, and 2

After "application", insert ";and".
Delete the remainder of this paragraph in its entirety.

Page 4
Section 2(2)(a)
Lines 1 and 2

Delete lines 1 and 2 in their entirety.

Page 4
Section 2(2)(b)
Line 3 and 4

After "(b)", delete the following:
In the event the State Health Plan does not address the proposed health facility or service,
Capitalize "if".

Line 4 and 5

After "applicant has", delete the following:
identified a need for the proposal for the geographic service area defined in the application and has

Line 6

After "identified", insert the following:
in the geographic service area defined in the application

Page 4
Section 2(3)
Line 9

After "proposed", insert a period.