TEAM KENTUCKY®

CABINET FOR HEALTH AND FAMILY SERVICES

Certificate of Need (CON) Task Force

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What are CON Programs?

A CON program is a state regulatory tool that controls the number of health care resources in an area. CON laws require a health care provider to demonstrate a need in the community before establishing or expanding a health care facility or service.

State CON laws differ, but generally address:

- The types of health care facilities that require CON
- Activities that trigger CON review
- The agency that reviews applications
- The information considered during a CON review

Legislative Findings and Purpose

Originally adopted in July 1980, KRS 216B.010 envisioned Kentucky's CON Program would result in cost-containment, improve quality, and increase access:

The General Assembly finds that:

- the licensure of health facilities and services is a means to insure safe, adequate, and efficient medical care;
- the proliferation of unnecessary health-care facilities, health services, and major medical equipment results in costly duplication and underuse; and
- proliferation increases the cost of quality health care.

It is the purpose of KRS Chapter 216B to authorize CHFS to perform any certificate-of-need function and other statutory functions necessary to:

- improve quality of health-care facilities, services, and providers;
- increase access to health-care facilities, services, and providers, and
- create a cost-efficient health-care delivery system for the citizens of the commonwealth.

Kentucky's Governing Statutes and Enabling Regulations

KRS Chapter 216B requires certain types of health care providers to obtain CON approval from the Cabinet for Health and Family Services before applying for licensure to operate a health facility or service.

The process by which potential health care providers can obtain a CON is governed by both statute and regulation.

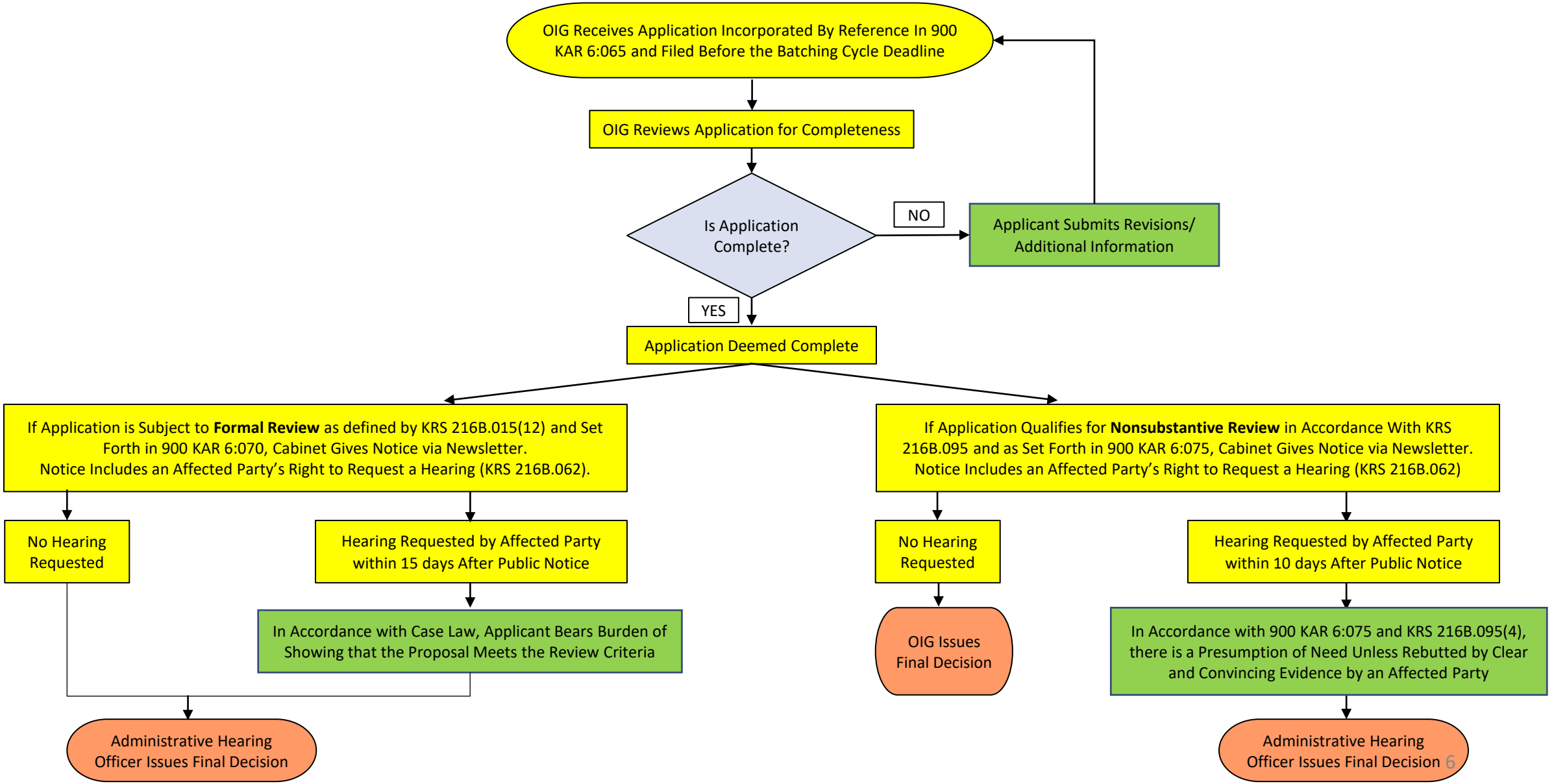
- **KRS Chapter 216B** allows an affected party to request a public hearing, establishes nonsubstantive review, prohibits the transfer of a CON, and requires notice to the cabinet of acquisitions and other actions that may require a CON.
- **900 KAR 5:020** incorporates the State Health Plan, which contains formulas and other criteria to determine whether there is a documented need for a particular health facility or service.
- **900 KAR 6:010 through 6:130** establish CON review procedures, application procedures, reasonable fees, notice provisions, procedures for review of completeness of applications, and timetables for review cycles.

CON Review Criteria

KRS 216B.040(2)(a)2. establishes the five criteria used to evaluate a CON application, including consistency with the State Health Plan. The criteria are summarized in the following chart:

Consistency with the State Health Plan	Need and accessibility	Interrelationships and linkages	Costs, economic feasibility, and resource availability	Quality of Care
The State Health Plan outlines the numerical need criteria by which CON applications are assessed by the cabinet. The applicant must show the proposed facility is consistent with the state's assessment of need for various health services.	The proposal must meet an identified need in a defined geographic area and be accessible to all residents of the area.	The proposal must serve to accomplish appropriate and effective linkages with other services, facilities, and elements of the healthcare system in the region and state, accompanied by assurance of effort to achieve comprehensive care, proper utilization of services, and efficient functioning of the healthcare system.	The proposal, when measured against the cost of alternatives for meeting needs, must be an effective and economical use of resources, not only of capital investment, but also ongoing requirements for health manpower and operational financing.	The applicant must be prepared to and capable of undertaking and carrying out the responsibilities involved in the proposal in a manner consistent with appropriate standards and requirements assuring the provision of quality healthcare services, as established by the cabinet.

CON Application Review Flowchart



What is Formal Review?

- Formal review is the most common and most complex CON application process.
- The applicant bears the burden of showing the proposed health service meets all five review criteria established by KRS 216B.040(2)(a), including consistency with the State Health Plan.
- A decision is rendered by a cabinet hearing officer approximately six months after the application date.

Formal Review is Required for the Following:

- Ambulance services, *unless a statutory exception applies*
- Ambulatory surgical centers
- Chemical dependency treatment programs
- Home health agencies
- Hospices, *including residential hospice if provided by a non-hospice entity*
- Hospitals
- Long-term care facilities, *excluding family care homes and assisted living communities*
- Freestanding or mobile technology
- Open heart surgery programs
- Organ transplant programs
- Prescribed pediatric extended care facilities
- Psychiatric residential treatment facilities, Level I and Level II
- Special care neonatal beds

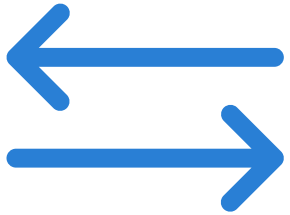
What is Nonsubstantive Review?

- Nonsubstantive review of a CON application is an expedited process for certain health services designated by statute or regulation (most have no established criteria in the State Health Plan).
- Although an "affected party" (e.g., a health care provider of similar services in the same service area) may contest a CON application, nonsubstantive review generally offers a smoother pathway to CON approval.
- There is a presumption of need unless rebutted by clear and convincing evidence by an affected party.
  - In contrast, the formal review process places the burden on the applicant to produce evidence of compliance with the review criteria in KRS 216B.040(2).

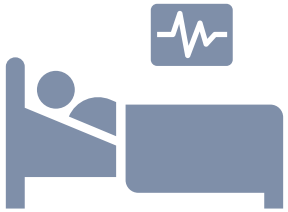
Statutory Authority for Nonsubstantive Review

KRS 216B.095 authorizes nonsubstantive review for a CON application:

To change the location of a proposed health facility



To replace or relocate a licensed health facility, if there is no substantial change in health services or substantial change in bed capacity



To replace or repair worn equipment if the worn equipment has been used by the applicant in a health facility for five years or more

For cost escalations

In other circumstances the cabinet by administrative regulation may prescribe

Nonsubstantive Review Status is Granted to:

- Acute care hospitals seeking to transfer acute care beds to a new facility under common ownership/in the same county and in accordance with additional criteria established by 900 KAR 6:075, Section 2(3)(f)
- Acute care hospitals seeking to convert existing acute care beds to psychiatric beds for adult patients in accordance with the criteria established by 900 KAR 6:075E, Section 2(3)(h)
  - Filed on March 15, 2023
- Adult day health centers
- Certain ambulance providers

  Effective July 14, 2022 through July 1, 2026, HB 777 grants nonsubstantive review status in accordance with KRS 216B.020(9) to:
  - City or county-owned ambulance providers that seek to provide non-911 transports
  - Hospitals that seek to provide ambulance transports from a location that is not a health facility
- Industrial ambulance providers
- Freestanding birthing centers
- Freestanding emergency department owned by a KY-licensed hospital and located off-campus
- Private duty nursing agencies
- Program of All-Inclusive Care for the Elderly (PACE) organizations that provide a CON service (e.g. adult day, home health) directly to their members

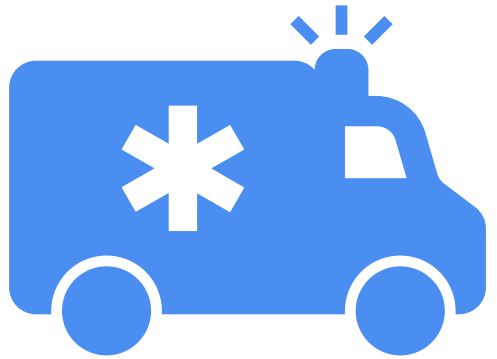
CON Exemptions Authorized by State Law

Health care providers that wish to initiate or expand health services in Kentucky are subject to CON approval unless they are exempt under KRS 216B.020(1) as follows:

- Abortion facilities
- Alcohol and drug prevention programs
- Alcohol and other drug treatment entities
- Ambulatory infusion agencies
- Assisted living communities
- Behavioral health services organizations
- Blood establishments
- Community mental health centers
- Family care homes
- Group homes
- Home health services provided by a certified continuing care retirement community to its on-campus residents
- Hospital-owned pain management clinics
- Nursing home beds exclusively limited to on-campus residents of a certified continuing care retirement community
- Renal dialysis facilities
- Residential hospice facilities established by licensed hospice programs
- Residential crisis stabilization units
- Specialty intermediate care clinics
- State Veterans' nursing homes

Exemptions for Certain Ground Ambulance Services

- **KRS 216B.020(6) exempts city-owned ambulance services that provide transport in a coterminous city outside of its service area if the cities have an agreement.**
- **Effective until July 1, 2026, HB 777 created a CON exemption in KRS 216B.020(7) for hospital-owned ambulance services that provide non-emergency or emergency transport originating from the hospital.**
  - A hospital-owned ambulance service that is exempt may also provide transport from another health facility to its hospital if "authorized" by the ambulance provider in the other facility's service area (KRS 311A.025).
- **Effective until July 1, 2026, HB 777 created a CON exemption in KRS 216B.020(8) for or cities or counties seeking to provide emergency ambulance transport services under the following conditions:**
  - The city or county government has conducted a public hearing to demonstrate an imperative need to provide emergency transport within the city or county and it will:
    - Directly provide emergency transport within its jurisdictional boundaries; or
    - Enter into a contract with a hospital located within its jurisdiction or in an adjacent county if there is no hospital in its county.



Private Practice Exemption from CON and Licensure

KRS 216B.020(2) exempts private offices and clinics from both the CON process and health facility licensure if the practice claiming the exemption is 100 percent owned by a Kentucky-licensed physician(s) or other practitioner(s) of the "healing arts" defined by KRS 311.271(2).

- *In accordance with KRS 216B.020(2)(a), the private practice exemption from CON and licensure does not apply to a physician's office that:*
  - *Provides outpatient surgical services*
  - *Requests an expenditure that exceeds the major medical equipment minimum*

A practitioner-owner that qualifies for the private practice exemption must maintain overall responsibility for directing and coordinating the care and management of services provided to patients.

Additional Exemptions from CON and Licensure

The 2018 passage of HB 444 amended KRS 216B.020 to establish an exemption from CON and health facility licensure for outpatient facilities that provide nonemergency, noninvasive services equivalent to the types of services provided in a private office or clinic, including:

- Primary care centers
- Special health clinics such as weight loss clinics, speech and hearing clinics, wellness centers, sports medicine clinics, dental clinics, and other medical specialty clinics
- Retail-based clinics
- Ambulatory care clinics treating minor illnesses and injuries
- Outpatient rehabilitation services
- Rural health clinics
- Networks and off-campus, hospital-acquired physician practices

Although rural health clinics and outpatient rehabilitation services are no longer subject to health facility licensure, the OIG continues to conduct surveys for those facilities that are federally certified as:

- Rural health clinics
- Comprehensive outpatient rehabilitation facilities
- Outpatient physical therapy/speech pathology services

Pending Regulations

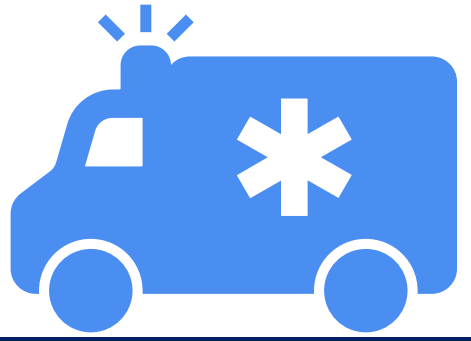
In accordance with the requirement of KRS 216B.015(28) for an annual update of the State Health Plan, the OIG filed 900 KAR 5:020 and 900 KAR 6:075 on March 15, 2023. The proposed changes include the following:

- Allows acute care hospitals to convert existing acute care beds to psychiatric beds for adult patients – nonsubstantive review
- Deletes outdated language referring to tuberculosis beds
- Allows a long-term care pediatric facility to add 50 or fewer beds
- Allows an acute care hospital, a critical access hospital, or a nursing facility to provide home health services to their patients – nonsubstantive review
- Makes megavoltage radiation, MRI, and PET applications subject to nonsubstantive review
- Broadens what qualifies as an ophthalmological ambulatory surgical centers

The OIG is currently preparing Statements of Consideration in response to public comments on both regulations.

Emergency Circumstances – Pending Regulation

- In an effort to help address situations in which an ambulance provider surrenders its license or had its license suspended, the cabinet filed 900 KAR 6:080E on May 19, 2023, to expand eligibility under the “emergency circumstances” regulation.
- Under the regulation, a county government seeking a temporary Class I hardship license from the Kentucky Board of Emergency Medical Services may begin providing ambulance services without first obtaining CON approval if continuous ambulance services in the area have ceased.
- This will allow an ambulance provider to quickly begin serving an area where continuous ambulance services are no longer available without waiting months to obtain a CON.
- The public comment period for 900 KAR 6:080E ends on July 31st.
  - The public comment period on 900 KAR 6:080, the identical “ordinary” version of the regulation, ends on August 31st.



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