

AMBULATORY CARE CENTERS

I. DEFINITIONS

A. Private Office Practice of Health Professionals: Private office practice of health professionals is the private office practice of any one or more health professionals licensed to practice in the state providing outpatient care. Private office practices have a separate and independent financial and administrative status. The organizational structure of the practice may be individual, partnership, or professional corporation. Practice will include professional services and other basic primary care services as defined by the Office of Community and Rural Health. Private office practice is exempt from Certificate of Need review. A facility which meets any part of the definition of Ambulatory Care Center set forth below is not a private office practice for purposes of this standard and is subject to review as an ambulatory care center.

B. Ambulatory Care Center: For purposes of this standard, a free-standing facility, staffed by one or more health care professionals, which provides services on an outpatient basis is an ambulatory care center if:

1. The facility acquires medical equipment, over a period of two years, with a value in excess of the statutory threshold for major medical equipment; or
2. The facility falls within one of the following categories of ambulatory care centers:
 - a. Community-Based Primary Care Center: A community-based primary care center is a primary care facility operated by a tax exempt, nonprofit organization with a community board that provides or will provide primary care services to people without regard to ability to pay and offers health education and preventive services to people in its service area.

Primary care services shall be defined by the Office of Community and Rural Health of the Department of Health and Human Resources. To qualify as a community board, a board must have sufficient community representation to allow that board to qualify as a board of a federally qualified health center. Additional relevant definitions are listed in Section III(A), below.

- b. Urgent Care Center: Urgent Care Centers are free-standing medical care centers which may be proprietary or non-profit. A wide range of

services may be provided by Urgent Care Centers: medical care for minor injuries or symptoms, drug screening or dispensing, primary care, pediatrics, orthopedics, physical or occupational therapy, gynecology, ENT, minor surgery, dermatology, cancer screening, diet control, psychological and allergy testing, simple diagnostic procedures and radiology.

In order to qualify as an Urgent Care Center, a facility must be open for more than 60 hours per week.

An Urgent Care Center is subject to the criteria and standards set forth below if it involves the acquisition, over a period of two years, of medical equipment with a value in excess of the statutory threshold for major medical equipment.

- c. Diagnostic Center: A Diagnostic Center is a facility that offers routine diagnostic outpatient testing and procedures, including, but not limited to laboratory, radiography, ultrasound, testing for general physical examinations, drug screening, nuclear medicine, imaging, or other procedures that can be reasonably performed in an outpatient setting. For the purposes of this standard, a Diagnostic Facility is subject to the criteria and standards set forth below if it involves the acquisition, over a period of two years, of medical equipment with a value in excess of the statutory threshold for major medical equipment.
- d. Ambulatory Surgery Center: Ambulatory surgery is the provision of surgical services that require anesthesia or a period of post operative observation or both, to patients whose admission for an overnight stay is not anticipated. Beds for overnight confinement are not provided.

Four Types of Ambulatory Surgery Centers

- 1) Free-Standing (a totally independent, separate facility). Such facilities shall have at least four operating suites.
- 2) Hospital-based independent (physically located within a hospital complex, but having a separate and independent financial and administrative status). Such facilities shall have at least four operating suites. These facilities shall be reviewable under CON for Ambulatory Surgery Centers.
- 3) Outpatient Surgery, referred to as hospital-based dependent (a facility which is financially and administratively linked to the hospital).

Such facilities shall have at least four operating suites. These facilities shall be reviewable as an Ambulatory Surgery Centers if associated costs are above the threshold for CON. This definition does not include the legally authorized practice of surgery by any one or more persons in the private offices of any health care providers except as outlined below.

4) Private Office Practice Surgical Facility (a facility which is part of a private office practice). Excepting the facilities of oral surgeons and podiatrists, such facilities shall be reviewable under CON under the following circumstances:

- a) if there are two or more operating room suites;
- b) if general, epidural, or spinal anesthesia is provided; or
- c) if the physician charges an additional fee for the use of the facility.

For the purposes of this definition, any Ambulatory Surgery Center is subject to the criteria and standards set forth below if it involves the acquisition, over a period of two years, of medical equipment with a value in excess of the statutory threshold for major medical equipment.

- e. Outpatient Behavioral Health Facility: Outpatient behavioral health facilities are defined as specialized health care services, which are provided by licensed health professionals and are concerned with patients with behavioral disorders, mental deficiencies or brain tissue impairments, provided on an outpatient basis that may be acute or long term in duration.

For purposes of this definition, an outpatient behavioral health facility is subject to the criteria and standards set forth below if it involves the establishment of a new institutional health service.

- f. Any other ambulatory health care facility, as defined by W.Va. Code 16-2D-2(b).

II. GENERAL STANDARDS

The following standards apply to all ambulatory care centers. Standards which apply specifically to a particular type of ambulatory care center are listed in Section III of this standard and supplement the general standards, unless otherwise noted.

A. Need Methodology

For ambulatory care centers for which no specific need methodology is set forth in Section III, below, the following general need methodology shall be used. If a need methodology is specified for a particular type of ambulatory care facility in Section III of this standard, the general need methodology will apply only to those portions of the need methodology which are not specified.

All certificate of need applicants shall demonstrate, with specificity, that there is an unmet need for the proposed ambulatory care services, that the proposed services will not have a negative impact on the community by significantly limiting the availability and viability of other services or providers, and that the proposed services are the most cost effective alternative.

The applicant shall delineate the service area by documenting the expected areas around the ambulatory care facility from which the center is expected to draw patients. The applicant may submit testimony or documentation on the expected service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services.

The applicant shall document expected utilization for the services to be provided by the facility for the population within the service area. As used in this section, "expected utilization", in addition to the expected demand for the service, may be expressed as the number of providers typically required to serve any given population, or as the number of persons in a population that are typically served by a single provider. Where a population is known to have specific characteristics, such as age or disease rates, that affect utilization, then those characteristics may be taken into consideration.

After establishing expected utilization or demand, the applicant shall estimate or document the number of existing providers within the service area and the extent to which the demand is being met by existing providers located within the service area. Where expected utilization is expressed as a number of providers typically serving a given population, it shall be sufficient to show that the ratio of providers to the population in the area is below the expected number. Providers located outside the service area need not be considered, absent specific showing that a provider located outside the service area is a major provider of services to the population within the service area.

B. Quality

Applicants seeking a certificate of need approval for the development of an ambulatory care center, or for a renovation project or replacement facilities, shall demonstrate compliance with applicable licensing, certification, and/ or accreditation standards, or submit a substantive and detailed plan to come into compliance with applicable licensing, certification and/or accreditation requirements. All staff of the facility shall be in compliance with applicable standards.

All ambulatory care centers shall document written plans for the development and implementation of a quality assurance program which meets acceptable standards as specified by any applicable accrediting organizations.

All ambulatory care centers shall demonstrate:

1. suitability of physical plant, if applicable;
2. adequate staff;
3. effective treatment environment documented by written protocol;
4. recognition of patient rights; and
5. an administration/evaluation process.

C. Continuum of Care

Ambulatory care centers will develop referral relationships and cooperative agreements with other health care providers as may be required to assure a continuum of care.

D. Cost

The financial feasibility of a proposed ambulatory care center must be demonstrated through three years.

Costs and charges for services and procedures provided in an ambulatory care center shall be comparable to the cost and charges of facilities offering comparable services, as defined by the Health Care Cost Review Authority, except where sliding fee arrangements exist based on patients' ability to pay.

Applicants must demonstrate in their financial projections that all indigent persons needing the services or procedures can be served without jeopardizing the financial viability of the project.

Applicants must demonstrate that new services, facilities and technologies will not lead to unnecessary increases in costs.

E. Accessibility

Facilities shall comply with all applicable state and federal laws regarding accessibility to the disabled.

Preference will be given to applicants who demonstrate intent to provide services to all patients, without regard to their ability to pay.

F. Alternatives

Alternatives to new construction should be explored and applicants must demonstrate the need for any new construction proposed for the development of an ambulatory care center.

Other alternatives which can assure the availability of the service at a lower or similar cost with improved accessibility shall be addressed.

G. Other

Notwithstanding their location in an ambulatory care center, nothing in this standard shall exempt from review certain health services, major medical equipment, and/or facilities, which are subject to separate certificate of need review pursuant to West Virginia Code. These include, but are not limited to:

Computerized Tomography
Proton Emission Tomography
Magnetic Resonance Imaging
Cardiac Catheterization
Radiation Therapy
Lithotripsy

III. FACILITY-SPECIFIC STANDARDS

A. Community-based Primary Care Centers:

1. Definitions:

- a. Primary care shortage area: A primary care shortage area is a geographic area that is underserved with respect to primary care

services. An area is considered a primary care shortage area if either of the following are true:

(1) The services are not located within the service areas of other comprehensive community-based primary care centers; or

(2) The services are located at least the allowable distance from other comprehensive community-based primary care centers.

- b. Rural: An area is considered "rural" if it does not contain a municipality with a population over 20,000 people.
- c. Allowable distance: In rural areas, for primary roads in non-mountainous terrain, twenty (20) miles; for primary roads in mountainous terrain, fifteen (15) miles; for interstates or other limited access highways, twenty-five (25) miles. In non-rural areas, for areas linked primarily by primary roads, seven (7) miles; and for areas linked primarily by interstates and other limited access highways, ten (10) miles.
- d. Service area: For each community-based primary care center, the service area is the geographic area or population groups approved by the Public Health Service of the United States Department of Health and Human Services as such center's service area. If a community-based primary care center does not report its service area to the Public Health Service, such center shall obtain approval of its service area from the Office of Community and Rural Health of the Department of Health and Human Resources.
- e. Comprehensive primary care center: A comprehensive community-based primary care center is a primary care center that is staffed at least thirty two (32) hours per week and offers a full range of primary care services.

2. Need Methodology:

- a. Replacement or maintenance of existing primary care services:

Community-based primary care centers proposing to replace or maintain existing primary care services shall have already satisfied the need requirement for replacing or maintaining such services, even if those services are offered in another location, as long as the proposed services serve the same population. To the extent that a certificate of

need is required to replace or maintain services, the agency shall not deny a request for such certificate of need on the basis of lack of need.

b. Creation of new primary care services:

(1) Primary care shortage area: Community-based primary care centers applying for certificates of need to create new primary care services shall have already satisfied the need requirement if the application establishes that such services are to be located in primary care shortage areas. The agency shall not deny such applications on the basis of need.

(2) Non-Primary care shortage areas: The agency shall evaluate need in the following manner for CON application by community-based primary care centers to create new primary care services in non-primary care shortage areas: a community-based primary care center proposing to add primary care services to a non-primary care shortage area shall satisfy the need requirement if no other community-based primary care center serving the same area demonstrates with specificity, within sixty days after the submission of a detailed description of such proposed new services to the agency and to all community-based primary care centers serving said area, either the lack of need for such services in the affected communities or the ability of the already existing center to provide such new primary care services within one year.

3. Quality:

All new primary care services regulated by this standard shall include a quality assurance program that is at least as stringent as required for federally qualified health centers, generally. The ratio of medical support staff to physicians shall not exceed four to one.

4. Cost:

All community-based primary care centers proposing new primary care services pursuant to this standard must demonstrate the financial ability to create and maintain such services. Charges for new primary care services shall be consistent with allowable costs of providing such services as determined by standards enforced by state and federal agencies. Salaries shall be comparable to salaries of other similar positions in the surrounding region.

5. Accessibility:

All community-based primary care centers proposing new primary care services pursuant to this standard must demonstrate how transportation will be provided for patients in the area who lack access to adequate transportation.

B. Ambulatory Surgery Centers:

1. Current Inventory:

The Health Care Cost Review Authority shall provide each applicant with a current inventory of ambulatory surgery centers and operating room suites.

2. Need Methodology:

Proposals involving building a new ambulatory surgery center, expanding an existing surgical facility, or replacing existing surgical capacity at the facility (based on the criteria set forth below) which would duplicate existing under-utilized facility capacity and are likely to lead to increases in the total cost of health care to a community may be denied by the HCCRA. In addition to meeting the 40 hour utilization minimum for new operating rooms at the facility, and the 36 hour minimum for the replacement or renovation of existing operating rooms at the facility, the applicant must submit reliable, probative, and substantial evidence documenting that it is not practical for the existing operating rooms at the facility to be utilized to achieve the required patient surgical requirements.

a. For New Operating Suites in Existing Facilities: Additional surgical suites shall not be added unless all existing comparable operating rooms at the facility are utilized on average for surgery at least 40 hours per week, including billable hours and reasonable turn-around time, based on the most recent 12 month study period for which data is available.

b. For Renovation or Replacement of existing Operating Suites: Renovation or replacement of surgical suites shall not be approved unless all existing comparable operating rooms at the facility are utilized for surgery on average at least 36 hours per week, including billable hours and reasonable turn-around time, based on the most recent 12 month study period for which data is available.

c. For New Operating Suites in New Freestanding Facilities or Private Office Practice Surgical Facilities: Additional facilities with operating

suites shall not be added unless all existing comparable operating rooms at other existing facilities in the area are utilized on average for surgery at least 40 hours per week, including billable hours and reasonable turn-around time, based on the most recent 12 month study period for which data is available.

Using the methodology below, the applicant shall demonstrate that the proposed operating room suites fall within the range of projected ambulatory surgical operating room suites for the service area.

The total number of operating room suites in the service area shall be defined by the following formula:

(1) Calculation of Use Rates Per 1,000 Population

- A. National Surgical Use Rate = $\frac{\text{Surgical Procedures for year}}{\text{year} \times 1000 \text{ U.S. population for year}}$
- B. West Virginia Surgical Use Rate = $\frac{\text{WV Surgical Procedures for year} \times 1000}{\text{WV population for year}}$
- C. Service Area, Surgical Use Rate = $\frac{\text{Area Surgical Procedures for year} \times 1000}{\text{Area Population for year}}$

(2) Calculation for Range of projected Ambulatory Surgical Procedures for Service Area

- A. Projected Surgical Procedures for Area = $\frac{\text{Lowest Use Rate for year} \times \text{Area Population for year}}{1,000}$
- B. Range of Projected Ambulatory Surgical Procedures
 - Lower end of range = Projected Surgical Procedures for area x .40
 - Upper end of range = Projected Surgical Procedures for area x .60

(3) Calculation for Range of Projected Ambulatory Surgical Operating Rooms for Service Area

A. Range of projected Ambulatory Surgical Operating Rooms

$$\begin{array}{lcl} \text{Lower end} & = & \text{Lower end of range (2)B of projected ambulatory} \\ \text{of range} & & \text{surgical procedures MINUS number of} \\ & & \text{ambulatory surgeries performed in year} \\ & & \hline & & 1,200 \end{array}$$

$$\begin{array}{lcl} \text{Upper end} & = & \text{Upper end of range (2)B of projected ambulatory} \\ \text{of range} & & \text{surgical procedures MINUS number of} \\ & & \text{ambulatory surgeries performed in year} \\ & & \hline & & 1,200 \end{array}$$

Assumptions of the methodology

- A. 40% to 60% of all surgeries performed in hospitals are appropriate for ambulatory surgery.
- B. 1,200 procedures per year are necessary to justify one ambulatory surgical operating room -- Source: Hospital Survey Committee of Philadelphia.
- C. National Surgical Use Rate of 110.5/1000 -- Source: American Medical Association.

3. Quality:

The applicant must demonstrate that it has entered a written agreement with the nearest acute care hospital, or any acute care hospital within thirty minutes travel time, stating that the acute care hospital will accept the transfer and care of patients from the ambulatory surgery center.