STATE OF TENNESSEE

STATE HEALTH PLAN

CERTIFICATE OF NEED STANDARDS AND CRITERIA

FOR

AMBULATORY SURGICAL TREATMENT CENTERS

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to establish or expand Ambulatory Surgical Treatment Centers (ASTCs). Existing ASTCs are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for the establishment or expansion of an ASTC.

These standards and criteria are effective immediately as of May 23, 2013, the date of approval and adoption by the Governor of the State Health Plan changes for 2013. Applications to establish or expand an ASTC that were deemed complete by the HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

1. "Ambulatory Surgical Treatment Center" (ASTC) shall have the meaning set forth in the Rules of the Tennessee Department of Health, Board for Licensing Health Care Facilities, Chapter 1200-08-12, or its successor.

2. "Full Capacity" shall mean:
   For a dedicated outpatient Operating Room: 1,263 Cases per year[1]
   For a dedicated outpatient Procedure Room: 2,667 Cases per year

3. "Operating Room" shall mean a room at an ASTC where general and/or Monitored Anesthesia Care (MAC) (the ability to administer general anesthesia) is employed. Any

[1] From information provided at the Public Meeting, the Division of Health Planning believes the previous 1,333 number is high and is lowering this calculation by increasing the estimated average time per Case in an Operating room from 60 to 65 minutes, resulting in a "Full Capacity" number of 1,266 Cases for an Operating Room.

level of sedation or anesthesia can be utilized in Operating Rooms as the anesthesia equipment is present in the room.

4. "Procedure Room" shall mean a room at an ASTC where local and/or intravenous sedation is employed.

    1. If an applicant intends to utilize an Operating Room or Procedure Room for types of sedation other than are set forth in the above definitions or for no type of sedation, it must provide information in its application setting forth the reasons for employing such different sedation type(s) (or lack thereof) and identify the types of Cases so impacted..

5. "Optimum Utilization" shall mean:
    2. For a dedicated outpatient Operating Room, 70% of Full Capacity
    3. For a dedicated outpatient Procedure Room: 70% of Full Capacity

6. "Service Area" shall mean the county or counties represented by the applicant as the reasonable area to which the facility intends to provide services and/or in which the majority of its service recipients reside.

7. "Specialty ASTC" shall mean an ASTC that limits its Surgical Cases to specific types.

8. "Case" shall mean one visit to an Operating Room or to a Procedure Room by one patient, regardless of the number of surgeries or procedures performed during that visit.

Assumptions in Determination of Need

The need for an ambulatory surgical treatment center shall be based upon the following assumptions:

1. Operating Rooms
    a. An operating room is available 250 days per year, 8 hours per day.
    b. The estimated average time per Case in an Operating Room is 65 minutes.
    c. The average time for clean up and preparation between Operating Room Cases is 30 minutes.
    d. The optimum utilization of a dedicated, outpatient, general-purpose Operating Room is 70% of full capacity. 70% x 250 days/year x 8 hours/day divided by 95 minutes = 884 Cases per year.

2. Procedure Rooms
    a. A procedure room is available 250 days per year, 8 hours per day.
    b. The estimated average time per outpatient Case in a procedure room is 30 minutes.
    c. The average time for clean up and preparation between Procedure Room Cases is 15 minutes.
    d. The optimum utilization of a dedicated, outpatient, general-purpose outpatient Procedure Room is 70% of full capacity. 70% x 250 days/year x 8 hours/day divided by 45 minutes = 1867 Cases per year.

Determination of Need

1. Need. The minimum numbers of 884 Cases per Operating Room and 1867 Cases per Procedure Room are to be considered as baseline numbers for purposes of determining Need.[2] An applicant should demonstrate the ability to perform a minimum of 884 Cases per Operating Room and/or 1867 Cases per Procedure Room per year, except that an applicant may provide information on its projected case types and its assumptions of estimated average time and clean up and preparation time per Case if this information differs significantly from the above-stated assumptions. It is recognized that an ASTC may provide a variety of services/Cases and that as a result the estimated average time and clean up and preparation time for such services/Cases may not meet the minimum numbers set forth herein. It is also recognized that an applicant applying for an ASTC Operating Room(s) may apply for a Procedure Room, although the anticipated utilization of that Procedure Room may not meet the base guidelines contained here. Specific reasoning and explanation for the inclusion in a CON application of such a Procedure Room must be provided. An applicant that desires to limit its Cases to a specific type or types should apply for a Specialty ASTC.

2. Need and Economic Efficiencies. An applicant must estimate the projected surgical hours to be utilized per year for two years based on the types of surgeries to be performed, including the preparation time between surgeries. Detailed support for estimates must be provided.

3. Need; Economic Efficiencies; Access. To determine current utilization and need, an applicant should take into account both the availability and utilization of either: a) all existing outpatient Operating Rooms and Procedure Rooms in a Service Area, including physician office based surgery rooms (when those data are officially reported and available[3]) OR b) all existing comparable outpatient Operating Rooms and Procedure Rooms based on the type of Cases to be performed. Additionally, applications should provide similar information on the availability of nearby out-of-state existing outpatient Operating Rooms and Procedure Rooms, if that data are available, and provide the source of that data. Unstaffed dedicated outpatient Operating Rooms and unstaffed dedicated outpatient Procedure Rooms are considered available for ambulatory surgery and are to be included in the inventory and in the measure of capacity.

4. Need and Economic Efficiencies. An applicant must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON application to establish an ASTC or to expand existing services of an ASTC should not be approved unless the existing ambulatory surgical services that

[2] The Division recognizes that estimated or average cleanup/preparation times and Case times may vary significantly by specialty and type of Case.

[3] The Department of Health is currently in the rule-making process necessary to implement the statute requiring the collection of office-based surgery data (Public Chapter 373, 2007). The Division recognizes that the Department of Health does not have sufficient data available on hospital ambulatory/outpatient surgery rooms at this time to include them in the determination of need; however, the Division plans to work with stakeholders towards this goal.

provide comparable services regarding the types of Cases performed, if those services are know and relevant, within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above.

5. Need and Economic Efficiencies. An application for a Specialty ASTC should present its projections for the total number of cases based on its own calculations for the projected length of time per type of case, and shall provide any local, regional, or national data in support of its methodology. An applicant for a Specialty ASTC should provide its own definitions of the surgeries and/or procedures that will be performed and whether the Surgical Cases will be performed in an Operating Room or a Procedure Room. An applicant for a Specialty ASTC must document the potential impact that the proposed new ASTC would have upon the existing service providers and their referral patterns. A CON proposal to establish a Specialty ASTC or to expand existing services of a Specialty ASTC shall not be approved unless the existing ambulatory surgical services that provide comparable services regarding the types of Cases performed within the applicant's proposed Service Area or within the applicant's facility are demonstrated to be currently utilized at 70% or above. An applicant that is granted a CON for a Specialty ASTC shall have the specialty or limitation placed on the CON.

Other Standards and Criteria

6. Access to ASTCs. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility.

7. Access to ASTCs. An applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available.

8. Access to ASTCs. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project the origin of potential patients by percentage and county of residence and, if such data are readily available, by zip code, and must note where they are currently being served. Demographics of the Service Area should be included, including the anticipated provision of services to out-of-state patients, as well as the identity of other service providers both in and out of state and the source of out-of-state data. Applicants shall document all other provider alternatives available in the Service Area. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

9. Access and Economic Efficiencies. An application to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters following completion of the project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

10. Patient Safety and Quality of Care; Health Care Workforce.

a. An applicant should be or agree to become accredited by any accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission, the Accreditation Association of Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgical Facilities, or other nationally recognized accrediting organization.[4]

b. An applicant should estimate the number of physicians by specialty that are expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel. An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.

11. Access to ASTCs. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

    a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;

    b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program;

    c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

    d. Who is proposing to use the ASTC for patients that typically require longer preparation and scanning times. The applicant shall provide in its application information supporting the additional time required per Case and the impact on the need standard.

[4] The Division recognizes that not all ASTCs can be CMS certified or accredited.

Rationale for Revised and Updated Standards and Criteria for Ambulatory Surgical Treatment Centers

Definitions

Operating Room/Procedure Room. The Division of Health Planning recognizes that there are vast differences in estimated utilization times and clean-up times for operating rooms and procedure rooms, and has worked with stakeholders to develop workable definitions to assist the HSDA in its deliberations. The Division recognizes that there remain measurable differences among the types of Cases performed in Operating Rooms, and among the type of Cases performed in Procedure Rooms, but is not comfortable at this time developing standards and criteria based on specific types of Cases. However, the revised and updated standards and criteria encourage applicants to provide information on variations from the standards and criteria to the HSDA to support a need determination that varies from the standards set forth herein. Additionally, the standards and criteria retain the ability of an applicant to apply for a Specialty ASTC.

Case. The previous Guidelines for Growth did not properly distinguish between "case" and "procedure." To solve this problem, which hindered the HSDA's ability easily to assess need, the Division has clarified this definition and deleted all references to "procedure."

Full Capacity. The Division solicited operating information from owners/operators of ASTCs. From this information, the Division learned there is significant variation in utilization between Operating Rooms and Procedure Rooms, as well as among Operating Rooms and among Procedure Rooms, depending on the type of Case. Based the information it received, the Division has developed a reasonable "base" capacity for an Operating Room and for a Procedure Room. Applicants may provide data that supports an application that varies from base capacity.

Future revisions to these standards and criteria may take into account Operating and Procedure Room capacity based on the type of Case. At this time, however the Division does not believe there is sufficient readily available data to enable applicants, opponents, and the HSDA for these types of revision.

Optimum Utilization. Based on information provided by stakeholders, a 70% optimum utilization standard is provided.

Standards and Criteria Regarding Certificate of Need Applications for Ambulatory Surgical Treatment Centers

Need: The Department of Health is currently in the rule-making process necessary to implement the statute requiring the collection of office-based surgery data (Public Chapter 373, 2007). The Division recognizes that the Department of Health does not have sufficient data available on

hospital ambulatory/outpatient surgery rooms at this time to include them in the determination of need; however, the Division plans to work with stakeholders towards this goal.

Access Issues: The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed service areas if that data are available. The majority of the population in a Service Area should reside within 60 minutes average driving time to the facility, and an applicant should provide information regarding the relationship of an existing or proposed ASTC site to public transportation routes if that information is available. Other standards and criteria are provided that provide demographic and geographic data on potential patients, as well as reinforcing the HSDA's own Rule regarding underserved populations and areas.

Economic Efficiencies: To support the goal of reducing health care costs, applicants should document all provider alternatives in a proposed Service Area. Additionally, projected utilization must be provided.

Quality of Care: The Division recognizes that not all ASTCs can be certified or accredited by the Centers for Medicare and Medicaid Services (CMS), but provides that an applicant should be accredited, or agreed to pursue accreditation, by an accrediting organization approved by CMS or by another nationally recognized accrediting organization.

Qualified and Sufficient Workforce: An applicant should provide documentation on the availability of appropriate and qualified staff that will provide ancillary support services, whether on- or off-site.