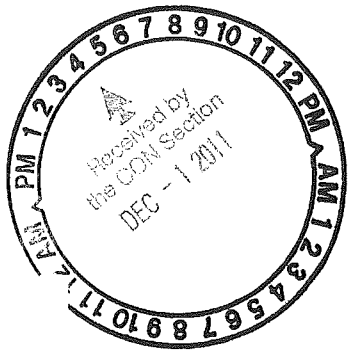
COMMENTS SUBMITTED BY HEALTHSOUTH CORPORATION
REGARDING PROJECT I.D. NO. F-8764-11
THE CHARLOTTE MECKLENBURG HOSPITAL AUTHORITY d/b/a CAROLINAS REHABILITATION
CERTIFICATE OF NEED APPLICATION FOR
RELOCATION OF INPATIENT REHABILIATION BEDS



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OVERVIEW

HealthSouth Corporation ("HealthSouth") is a provider of inpatient rehabilitation services. HealthSouth operates an inpatient rehabilitation hospital in Rock Hill, South Carolina, just a few miles from where The Charlotte Mecklenburg Hospital Authority d/b/a Carolinas Rehabilitation ("CMHA") proposes to relocate inpatient rehabilitation beds to the campus of CMC-Pineville.[1] *See* Exhibit A to these comments (Mapquest map showing distance between HealthSouth Rock Hill and CMC Pineville).[2]

HealthSouth Rehabilitation Hospital of Rock Hill (www.healthsouthrockhill.com) is a 46-bed acute medical rehabilitation hospital that offers comprehensive inpatient and outpatient rehabilitation services. Designed with patient care in mind, HealthSouth Rock Hill offers 18 private rooms and 28 semi-private rooms. Offering the latest rehabilitation technology, this

[1] The fact that HealthSouth is headquartered in Alabama and does not operate any inpatient rehabilitation hospitals in North Carolina does not impact its right to file comments on the CMHA application, and is not a factor that the Agency should consider in evaluating these comments. N.C. Gen. Stat. § 131E-185(a1)(1) allows any person (which is defined to include corporations) to file comments. Moreover, HealthSouth provides the identical services CMHA proposes to offer to some of the same patients CMHA proposes to serve. CMHA's proposed service includes South Carolina. *See* application, page 60. In prior reviews, the Agency has considered services that are available in other states when it is reviewing North Carolina CON projects. *See, e.g.,* Findings on Project I.D. No. F-7706-06 (CMHA's application to develop a healthplex and freestanding emergency department in Waxhaw, North Carolina), attached as Exhibit B.

[2] As the Agency is aware, inpatient rehabilitation hospital services tend to be more regional in nature than acute care hospital services. This is reflected on pages 60-61 of the application which show patient originating from thirty-one counties in North Carolina and South Carolina. In North Carolina, there are far fewer inpatient rehabilitation hospitals than there are acute care hospitals.

60,000-square-foot hospital serves patients throughout upstate South Carolina and southern North Carolina. HealthSouth Rock Hill therefore serves some of the same patients that CMHA proposes to serve in Pineville. HealthSouth's facility is new and has capacity to serve more patients. CMHA's proposal will directly and adversely impact HealthSouth Rock Hill.

At the outset, it is important to recognize that while CMHA is moving existing inpatient rehabilitation beds, as opposed to adding new beds, CMHA must nevertheless demonstrate that its proposal conforms with all applicable statutory review criteria, just like any other proposal. These criteria include demonstration of need (Criterion 3), demonstration that the proposal is the least costly or most effective alternative (Criterion 4), demonstration of financial feasibility (Criterion 5) and demonstration that the project avoids unnecessary duplication of existing services (Criterion 6). In addition, the applicant must also demonstrate that the population presently being served by these assets would not be harmed by the relocation of these assets to a different location (Criterion 3a). As explained in these comments, CMHA is unable to demonstrate that its project conforms with these criteria, among others.

In two recent reviews, the Agency has refused to allow applicants to move assets around where they failed to comply with the statutory review criteria. *See, e.g.,* Agency Findings on Wake Forest Ambulatory Venture's proposed relocation of three operating rooms from Winston-Salem to Clemmons; and Agency Findings on Mission's proposed relocation of a GI endoscopy room from Asheville to Fletcher (attached to these comments as Exhibits C and D).

These findings are instructive in this review. The ability to move assets does not justify moving them, and prior approvals to move inpatient rehabilitation beds within HSA III should not influence this application. HealthSouth does not find evidence supporting the need to relocate inpatient rehabilitation beds to Pineville, especially when HealthSouth Rock Hill is close by and has capacity to serve patients. Accordingly, CMHA's application should be denied.

CRITERION BY CRITERION ANALYSIS

Criterion 3

Criterion 3 states:

> *The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.*

Beginning in 2005, CMHA embarked on a significant re-distribution of inpatient rehabilitation beds in HSA III. First, in Project I.D. No. F-7317-05, CMHA moved 40 inpatient rehabilitation beds to Belmont, in Gaston County to establish CR-Mount Holly. Then, in 2008, it filed a CON application (Project I.D. No. F-8161-08) to relocate 40 inpatient rehabilitation beds (20 from CR-Mercy, 10 from CR-Main and 10 from Stanly) to a new facility in Cabarrus County, to be called CR-NorthEast. This project is under development.

Next, CMHA took 10 inpatient rehabilitation beds from Rowan Regional Medical Center (RRMC), which caused the temporary closure of that unit. On May 24, 2010, CMHA received a declaratory ruling to install those beds temporarily at CR-Main, and then finally at CR-Mercy, which it has not done. Now in 2011, a little more than one year after receiving the declaratory ruling, CMHA proposes to take the 10 RRMC beds that were supposed to go temporarily to CR-Main and ultimately to CR-Mercy, and 19 inpatient rehabilitation beds at CR-Mercy and establish a 29-bed inpatient rehabilitation unit at CMC-Pineville. Development of this project means that the inpatient rehabilitation unit at CR-Mercy, which has served the community for decades, will close.

This application raises many issues under Criterion 3, which are discussed below. As the Agency reviews this application, the core issue the Agency must consider is not whether CMHA has demonstrated the need for inpatient rehabilitation beds, but rather, whether CMHA has demonstrated the need for these beds *in Pineville*, especially when HealthSouth Rock Hill is close by and has capacity to serve patients.

On page 33 of the application, CMHA begins its discussion about the need for the project by noting that it will "relocate inpatient rehabilitation beds to the recently approved LTACH facility. . .. Co-locating inpatient rehabilitation beds in a facility with LTACH beds will afford multiple opportunities to utilize economies of scale to reduce the cost of providing care while, at the same time, providing a higher level of service."

CMHA never explains how this proposed relocation/co-location supports the need to relocate these beds to Pineville. CMHA does not quantify the economies of scale or explain exactly how co-locating these services will reduce cost. Nor does CMHA suggest that the only way to achieve economies of scale and to reduce cost is by co-locating these services. CMHA does not show any correlation between the number of LTACH patients who need inpatient rehabilitation services in the same building, or the number of inpatient rehabilitation patients who need an LTACH in the same building.[3]

Beginning on page 34 of the application, CMHA discusses "facility issues" at CR-Main. CMHA specifically focuses on the fact that there are nine "ward beds" and that adding the 10 beds that CMHA took from RRMC has "effectively increased the number of beds that are in semi-private and ward rooms." Application, page 35.

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[3]*See also* application, page 81, where CMHA notes "improved efficiencies via shared services with LTACH hospital" but does not describe what these efficiencies are or quantify them in any way. The application also does not describe whether any of the other improvements listed in the bullet points on page 81 could be achieved at CR-Main or CR-Mercy.

Yet in March 2010, CMHA specifically requested in a declaratory ruling request that it be allowed to relocate the 10 beds from RRMC first at CR-Main and then at CR-Mercy. The declaratory ruling request is in Exhibit 10 to the CON application. There is no discussion in this declaratory ruling request that indicates that CR-Main and CR-Mercy were ill-suited for inpatient rehabilitation beds. CMHA presumably understood the impact the relocation of the 10 RRMC beds would have on ward and semi-private rooms at CR-Main. According to page 19 of the application, these 10 beds have been in place at CR-Main since October 2010, where they have been used to treat patients. In fact, on page 5 of the declaratory ruling request, CMHA stated:

> *CR-Main provides inpatient rehabilitation services with eighty (80) inpatient rehabilitation beds. Currently, there are twelve (12) ward beds remaining at this facility. While ward beds were considered a 'standard of care' during the construction of CR-Main, the use of these beds has proven obsolete as a result of operational inefficiencies and patient dissatisfaction. As explained in the CR-Northeast CON Application, one the ten (10) rehabilitation beds are relocated from CR-Main to CR-NorthEast, CR Main will eliminate all ward rooms from the facility while effectively increasing the number of private rooms. . . .*
>
> *Further, CR-Main has existing space in which the 10 Rehab Beds from RRMC can be located. Prior to the relocation of beds to Carolinas Rehabilitation-Mt. Holly (CR-Mount Holly), CR-Main housed 120 inpatient rehabilitation beds.* ***Therefore temporarily increasing the number of inpatient rehabilitation beds at CR-Main does not create a hardship for the facility.***

(emphasis added).

Relying on these representations, the Department granted CMHA's request for declaratory ruling on May 24, 2010. *See* Exhibit 10 to the application. CMHA does not explain how increasing the number of inpatient rehabilitation beds at CR-Main became a problem a little more than a year later. It is also important to note that whatever facility issues may exist at CR-Main, the placement of the 10 beds there was only supposed to be temporary; the ultimate location for these beds was supposed to be CR-Mercy.

On page 36, CMHA states that "[t]he beds located at CR-Mercy are located on the 7th Floor of CMC-Mercy, in spaces designed for general acute care beds. The spaces were not designed for inpatient rehabilitation services, thus there are limitations that exist with the facility spaces." The March 2010 declaratory ruling request, however, does not state or imply that there are any "facility issues" at CR-Mercy that make the location of inpatient

rehabilitation beds at that facility infeasible.[4] Rather, CMHA told the Department that " . . . operating costs and charges will not increase when the beds are moved from CR-Main to CR-Mercy because the relocation of CR-Mercy beds to CR-NorthEast will leave available space for the rehabilitation beds at CR-Mercy. No upfit will be required when the 10 Rehab Beds are relocated to CR-Mercy." Exhibit 10 to the CMHA application, page 6.

CMHA does not explain what changed between March 26, 2010, the date CMHA submitted the declaratory ruling request, and October 17, 2011, the day that CMHA filed the CON application. If CR-Main and CR-Mercy had "facility issues," these facility issues likely would have been known to CMHA at the time of the declaratory ruling request. Presumably CMHA would have mentioned these issues in the declaratory ruling request, and included a capital cost for addressing these issues. CMHA does not provide any information about the costs or other considerations that would be involved in addressing these facility issues, in lieu of spending $18 million on the proposed facility. CMHA's discussion of "facility issues" at CR-Main and CR-Mercy does not adequately explain why CMHA needs to build an inpatient rehabilitation hospital in Pineville.

On page 36, under the heading "**NEED TO APPROPRIATELY REDISTRIBUTE BEDS IN HSA III,**" CMHA describes the multi-year inpatient rehabilitation bed shuffling it has been doing. According to CMHA, "[t]he proposed project now represents the next phase of bed decentralization for CR's facilities in Mecklenburg County." CMHA discusses how relocating a total of 29 beds from CR-Main and CR-Mercy "brings inpatient rehabilitation services in the local community to better serve patients and their families. Patients will no longer have to travel into a busy center city Charlotte to receive needed rehabilitative care." Application, page 37.

CMHA does not provide any empirical evidence, such as drive times, distances or traffic conditions, to demonstrate that patients have had difficulty accessing inpatient rehabilitation services in "busy center city Charlotte." Moreover, inpatient rehabilitation is not like an emergency department or an acute care hospital. At an inpatient rehabilitation facility, unlike a busy center city ED or acute care hospital, there are no crowds of people waiting to be seen and no trauma cases that may "bump" the less emergent cases.

CMHA does not provide any empirical evidence, such as drive times, distances or traffic conditions, to demonstrate that locating inpatient rehabilitation beds in Pineville is more convenient for patients and caregivers than going to center city Charlotte. Depending upon

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[4] It is also important to note that CMHA is proposing to add acute care beds to the seventh floor of CMC-Mercy in Project I.D. No. F-8763-11, which is currently under review. The space where these acute care beds will go on the seventh floor will be completely renovated to house the new acute care beds. This raises an important question: if the seventh floor of CMC-Mercy could be renovated to house acute care beds, could not renovations be done to the seventh floor of CMC-Mercy if needed to accommodate inpatient rehabilitation beds more appropriately? CMHA does not address this question. It is worth noting that the capital cost to develop the acute care beds at CMC-Mercy (which includes renovations on other floors of the hospital, not just the seventh floor) is $6,679,000, which is significantly less than the $17,748,729 CMHA proposes to spend on the CR-Pineville project. The alternative of renovating CR-Mercy is not discussed in the application. *See, e.g.*, pages 54-58 of the application (discussion of alternative).

where the patients and their caregivers live, it could be substantially less convenient, and more expensive, to travel to Pineville. Nothing in the application suggests that there are an appreciable number of inpatient rehabilitation patients living in or near Pineville who are not presently being, or may be, served by CR-Main, CR-Mercy, HealthSouth Rock Hill, or other facilities and who might be better served by the proposed inpatient rehabilitation facility in Pineville. There are no letters of support from patients or caregivers included in the application, so the application is devoid of empirical evidence suggesting that patients and caregivers believe that Pineville is an appropriate location for these inpatient rehabilitation beds.[5]

On page 38 of the application, CMHA continues its discussion about "busy and congested center city Charlotte," suggesting that Pineville is a comparative haven of tranquility. Pineville is a busy, growing suburb that sits close to the South Carolina border. It has a large shopping mall, schools, restaurants, and a hospital, CMC-Pineville, that is becoming a tertiary facility. For some, especially the elderly, the trip on I-485 to Pineville can be just as, if not more challenging, than a trip to "congested center city Charlotte." As CMC-Pineville grows into a tertiary center, the traffic on that campus is likely to increase, so the convenience benefits that CMHA describes on pages 37-40 of the application may be fleeting, if they exist at all. In any event, CMHA's conclusory analysis of convenience does not clearly demonstrate that these inpatient rehabilitation beds are needed in Pineville.

On pages 40 and 41 of the application, CMHA discusses the demographic need for inpatient rehabilitation services. CMHA observes, correctly, that Mecklenburg County is the largest county by population in the State of North Carolina. CMHA states that " . . .as the overall population increases in Mecklenburg County, the demand for inpatient rehabilitation services will continue to increase." Application, page 41. CMHA provides no empirical evidence to support this statement. More importantly, CMHA fails to explain how this statement, if true, supports the need for inpatient rehabilitation beds *in Pineville.*

From pages 42 to 52 of the application, CMHA provides its methodology for projecting utilization. This methodology is broken into three steps. In Step 1, CMHA reviews the historical utilization of inpatient rehabilitation beds at CR-Main and CR-Mercy. Despite the "facility issues" that are discussed earlier in the application, CMHA notes that both CR-Main and CR-Mercy have experienced a positive two-year compound annual growth rate (CAGR) in days of care. This step in the methodology does not support a need for beds *in Pineville.*

In Step 2, CMHA projects utilization in inpatient rehabilitation days of care. CMHA begins by projecting utilization for the interim years, *i.e.,* CY 2012 and CY 2013, and then CMHA projects utilization for the first three project years. Utilization is expected to increase in each of the first three project years. CMHA does not justify the increase, other than to state that "CR's projected utilization during the initial three project years is reasonable and conservative." Application, page 45. CMHA adds that "[t]he projected growth rate at CR-

[5] In Exhibit 20, the application includes six form letters of support from physicians. They do not provide any specific facts (such as number of patients who might benefit from inpatient rehabilitation beds in Pineville) demonstrating the need for the inpatient rehabilitation beds in Pineville.

Mercy (1.6 percent) is less than the two year CAGR for CR-Mercy's historical days of care (2.4 percent) and is also equivalent to CR-Mercy's most recent annual increase." Application, page 45. While this is literally true, this does not mean that CMHA's projections are "reasonable." CMHA notes that a decrease in ward and semi-private rooms will make CR-Main "better positioned to meet the current demand for inpatient rehabilitation services at its facility," but offered no explanation describing how ward and semi-private rooms have impacted CR-Main's utilization historically. Nor does any of this information explain why the beds are needed *in Pineville*, especially when HealthSouth Rock Hill is close by and has capacity to take on additional patients. There is no discussion in the application at all about HealthSouth's Rock Hill facility.

In Step 3, which goes on from pages 45 to 52, CMHA projects utilization for the relocated beds. The first several pages are devoted to a discussion about the impact of the CR NorthEast facility. This information is not relevant to this application.

On page 48, CMHA states that "CR projects that CR-Mercy's projected days of care for its remaining 19 beds will shift to CMC-Pineville for proposed project. It is reasonable to assume that remaining CR-Mercy projected days of care will shift to CMC-Pineville because the relocated beds will continue to provide the same services currently offered at CR-Mercy." This does not logically demonstrate that patients would choose to travel to Pineville. Indeed, they may just as well receive their inpatient rehabilitation care at CR-Main, which is projected to have 70 inpatient rehabilitation beds upon completion of this project. These beds are moving ten miles away; it cannot be assumed that simply because the same services will be offered that the patients will travel with the beds, especially since there will still be an inpatient rehabilitation option in downtown Charlotte. While CMHA states on page 48 that it reviewed patient origin and acuity, it does not provide the number of patients who now go to CR-Mercy and who live in or near Pineville. Rather, the Agency is simply asked to make an assumption, which it cannot do without adequate factual support. The CMHA application does not provide this evidence.

CMHA makes a similar unsupported assumption with regard to CR-Main. It states that it will shift about 12.5% of its licensed bed capacity to CMC-Pineville, and therefore, it projects to shift 8% of CR-Main's days of care to CR-Pineville during Project Year 1. But no explanation is provided as to why or how CMHA selected 8% as opposed to some other number. The fact that one number is lower than another number does not demonstrate the need for these beds *in Pineville.*

CMHA states that in Years 2 and 3 of the project, it increased the number of days to be shifted from CR-Main to CR-Pineville from 8% to 10%. As was the case with CR-Mercy, CMHA assumes the patients will follow the beds. But there is no factual support for this assumption, especially since 70 beds will remain at CR-Main.

On pages 50 and 51 of the application, CMHA states that it applied CR-Mercy's CY 2010 ALOS to the projected days of care at CR-Pineville. This assumes that the patients will follow the movement of the beds, but CMHA has not provided any factual support for this assumption.

On pages 51 and 52, CMHA concludes its need methodology by repeating some of its earlier statements about "busy center city Charlotte." As previously noted, there is no factual information in the application to show that having inpatient rehabilitation beds in busy center city Charlotte has impeded patient access, or conversely, that relocating beds to Pineville will improve patient access. By keeping 70 inpatient rehabilitation beds at CR-Main, CMHA appears to recognize the importance of having inpatient rehabilitation beds in busy center city Charlotte.

On pages 60-61, CMHA describes its projected patient origin for CR-Pineville. CMHA states that it based its patient origin on the historical CY 2010 patient origin for the 29 inpatient rehabilitation beds at CR-Mercy. In comparing the CY 2010 patient origin for CR-Mercy to the projected patient origin for CR-Pineville, however, it is unclear how exactly CMHA based the projected patient origin on the historical patient origin. For example, the percentage of Mecklenburg residents projected to be served is significantly higher at CR-Pineville (71.6%) than at CR-Mercy (64.4%). CMHA states that it deleted Cabarrus, Rowan and Iredell from the projected patient origin of CR-Pineville, and made proportionate adjustments to the patient origin for Mecklenburg and Union Counties. While this may be mathematically correct, it does not necessarily follow that because three counties were deleted that two other counties would experience a proportionate increase. In any case, the deletion of these three counties represents a change from CR-Mercy's historical patient origin, and does not support the statement that CR-Pineville's patient origin is based on CR-Mercy's patient origin.

At the same time, however, CMHA has held the patient origin for York County, South Carolina consistent at 3.4%, which seems questionable given that the beds are moving closer to South Carolina. It is also not clear why CMHA purports to base the patient origin on CR-Mercy rather than CR-Main. CMHA states that CR-Main serves patients with higher acuity because CR-Main is located adjacent to a trauma center. No data is provided showing the difference in acuity levels at the two inpatient rehabilitation facilities. No data is provided that correlates CMC's trauma center status to inpatient rehabilitation levels. No data is provided illustrating the number of trauma patients who were sent from CMC to CR-Main instead of CR-Mercy. CMHA suggests that because CR-Pineville will provide the same services at CR-Mercy, the patient origin "is not expected to change significantly." But, at least with respect to Mecklenburg and Union Counties, the patient origin *is* changing significantly. It also cannot be assumed that because the services will be the same as they are at CR-Mercy that CR-Mercy's patients will "follow" the beds to Pineville. Thus, the applicant has not adequately documented the assumptions and methodology used to project patient origin.

The applicant's payor mix (discussed in Section VI of the application) is based on a "blended" payor mix for CR-Mercy and CR-Main. *See* application, pages 90-91. CMHA does not explain why the projected payor mix would the same as the historical blended payor mix, when the patient origin is changing, as noted above. Since the location of the beds is changing, one would expect there to be some changes in patient origin, and therefore, changes to the payor mix.

Accordingly, CMHA has failed to demonstrate the need for this project under Criterion 3 and its application should be disapproved.

Criterion 3a

Criterion 3a states:

> *In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocated or by alternative arrangements, and the effect that the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.*

CMHA states on page 63 of the application that "[t]he relocation of inpatient rehabilitation beds from CR-Mercy will not have a negative impact on access to rehabilitation services in Mecklenburg County; rather it will greatly improve access to rehabilitation services." CMHA offers no factual support for these statements. There is no analysis contained in the application which shows how the move would impact patients. There is also no information in the application demonstrating that access to inpatient rehabilitation services in Mecklenburg County or the surrounding counties is in fact a problem. CMHA is a public hospital authority owned by the people of Mecklenburg County who support CMHA through their taxes. There is no evidence that any patients or their caregivers were consulted.

The application's nonconformity with Criterion 3a is highlighted by the fact that just over a year ago, CMHA asked for, and received, a declaratory ruling that allowed it to move inpatient rehabilitation beds from RRMC to CR-Main and then to CR-Mercy. This indicates that the beds were needed in central Charlotte, not elsewhere. No information is provided to show what if anything changed between May 24, 2010 and October 17, 2011.

Proximity to one's family and support system (*i.e.,* friends, work colleagues, church members, etc.) is vitally important to an inpatient rehabilitation patient's recovery. There is no discussion about how this bed relocation may impact those people. While a 10-mile distance may seem small, it is important to note that some caregivers are themselves elderly and infirm, so any additional travel they incur in order to visit their loved one may be difficult, expensive and potentially dangerous. No consideration appears to have been given to this critical point.

In addition, this project actually involves shutting down the inpatient rehabilitation unit at CR-Mercy. CR-Mercy has provided this service for decades. Closing this unit will be a

profound change for the community and for the patients served by this unit, but the application does not examine this important point.

Whenever a service or a facility is proposed to be shut down, as is the case here, the Agency should scrutinize the application carefully to make sure that the interests of patients presently being served by the service or facility are protected. Since the applicant did not provide the Agency with any factual information which the Agency could use to verify the applicant's statement that moving these beds "will not have any negative impact on the patients served," the Agency is compelled to deny the application under Criterion 3a.

Criterion 4

Criterion 4 states:

> *Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.*

Normally, when an application is non-conforming with Criterion 3, which is the case here, the application will also be found non-conforming with Criterion 4. There are alternatives to this project: leave the beds at CR-Main where they are and implement the declaratory ruling as proposed. This would be a far more cost-effective solution than the $18 million project now proposed by CMHA.

In Exhibit 10 to the CMHA application, the declaratory ruling request, CMHA represented on March 26, 2010 that:

> *Existing space in which to locate the 10 Rehab Beds is available at CR-Main without requiring construction. The only additional cost is the addition of another nurse call/pillow speaker device to each of the ten (10) rooms to house the 10 Rehab Beds. This is not a capital expense but an operational expense, and in any event, the total cost will be minimal and far below the $2 million threshold. Operating costs will not increase and charges to the patient while the beds are located at CR-Main will be the same as patient charges at CR-Main.*
>
> ***
>
> *No upfit will be required when the 10 Rehab Beds are located to CR-Mercy.*

Exhibit 10 to the application, page 6.

Thus, a project that was supposed to cost almost nothing is now going to cost almost $18 million. Notably, in the declaratory ruling request, there is no discussion about any facility issues that may have existed at CR-Mercy. CMHA specifically said in the declaratory ruling request that CR-Mercy was the appropriate place for the 10 beds relocated from RRMC.

The Department accepted CMHA's representations in 2010 and issued the declaratory ruling on May 24, 2010. *See* Exhibit 10 to the application. CMHA provides no information to explain what occurred between May 24, 2010 and October 17, 2011 that would justify the extraordinary departure from the representations in the declaratory ruling request.

The application should be found non-conforming with Criterion 4.

Criterion 5

Criterion 5 states:

> *Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs and charges for providing health services by the person proposing the service.*

Normally, when an application is non-conforming with Criterion 3, which is the case here, the application will also be found non-conforming with Criterion 5. Since CMHA failed to demonstrate the need for this project, it likewise cannot demonstrate the financial feasibility of the project. Therefore, the application should be found non-conforming with Criterion 5.

Criterion 6

Criterion 6 states:

> *The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.*

Normally, when an application is non-conforming with Criterion 3, which is the case here, the application will also be found non-conforming with Criterion 6. Since CMHA failed to demonstrate the need for this project, it likewise cannot demonstrate the financial feasibility of the project. Therefore, the application should be found non-conforming with Criterion 6.

There are two other points the Agency should consider under Criterion 6. First, as part of its Criterion 6 analysis, the Agency should consider that after this project is developed, CMHA will still have a 70-bed inpatient rehabilitation hospital, CR Main, less than 10 miles away. *See* Exhibit E (Mapquest map depicting location of CR-Main and CMC-Pineville).

Inpatient rehabilitation services are not the same as acute care hospital services. A 29-bed inpatient rehabilitation hospital is not needed within 10 miles of a 70-bed inpatient rehabilitation hospital, especially when both hospitals are owned by the same provider. Not every town or city needs an inpatient rehabilitation hospital, and there is no evidence in the application to suggest that residents of the Pineville area are having trouble accessing the inpatient rehabilitation beds at CR-Main and CR-Mercy. There is no evidence in the application to suggest that Mecklenburg County needs another inpatient rehabilitation hospital. Thus, CMHA is essentially duplicating itself in this proposed project.

Second, the Agency should consider that this facility will unnecessarily duplicate the services offered by HealthSouth Rock Hill. HealthSouth Rock Hill offers all of the same inpatient rehabilitation services that CMHA proposes to offer in Pineville. HealthSouth Rock Hill has capacity to treat more patients, and it already serves some of the same patients CMHA proposes to serve in its project. As shown in Exhibit A, HealthSouth Rock Hill is about 20 miles from the Pineville site. There is no need for another inpatient rehabilitation hospital in such close proximity to HealthSouth Rock Hill.

Criterion 18a

Criterion 18a states:

> *The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

Normally, when an applicant is non-conforming with Criterion 3, which is the case here, the applicant will also be found non-conforming with Criterion 18a. Thus, CMHA's application should be found non-conforming with Criterion 18a.

There is, however, another important fact that must be considered in connection with Criterion 18a: CMHA controls 95% of the inpatient rehabilitation beds in HSA III. This project does not foster competition when CMHA already controls 95% of the inpatient rehabilitation beds in HSA III. To the contrary, this project increases costs, decreases access at CR-Mercy, and appears to be an attempt by CMHA to serve the same patients HealthSouth Rock Hill already serves. HealthSouth Rock Hill is the only provider of inpatient rehabilitation services not owned by CMHA that is in the immediate vicinity of CMHA's project.

Accordingly, this application should be found non-conforming under Criterion 18a.

Criterion 20

Criterion 20 states:

> *An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.*

HealthSouth requests that the Agency adhere to its well-established practice of checking with the appropriate people in Licensure to determine whether there have been incidents bearing on quality care at any CMHA facilities, including but not limited to any that provide inpatient rehabilitation care, in the last 18 months.

CONCLUSION

For the reasons set forth in these comments, HealthSouth respectfully requests that the Agency deny the CON application for Project I.D. No. F-8764-11. HealthSouth respectfully requests that the Agency inform HealthSouth of its decision on this application.

HealthSouth appreciates the Agency's time and attention to these comments.

mapquest

Trip to:
10628 Park Rd
Charlotte, NC 28210-8407
20.23 miles
28 minutes

Notes

Distance from HealthSouth Rock Hill to CMC Pineville

Exhibit A

		Miles Per Section	Miles Driven
	1795 Dr Frank Gaston Blvd Rock Hill, SC 29732-1190		
	1. Start out going **southwest** on **Dr Frank P Gaston Blvd** toward **Herlong Ave S**.	**Go 0.3 Mi**	0.3 mi
	2. Turn **left** onto **Herlong Ave S**. *Bb&t is on the corner*	**Go 1.3 Mi**	1.5 mi
	3. **Herlong Ave S** becomes **India Hook Rd**.	**Go 1.0 Mi**	2.5 mi
161	4. Turn **right** onto **Celanese Rd / SC-161**. *Celanese Rd is just past Bayshore Dr* *If you are on India Hook Rd and reach Mills Park Dr you've gone about 0.1 miles too far*	**Go 2.2 Mi**	4.7 mi
NORTH 77	5. Merge onto **I-77 N** toward **Charlotte** (Crossing into **North Carolina**).	**Go 10.1 Mi**	14.8 mi
EXIT 1 EAST 485	6. Merge onto **I-485 E** via **EXIT 1** toward **Pineville**.	**Go 4.8 Mi**	19.6 mi
EXIT 64A NORTH 51	7. Merge onto **Pineville-Matthews Rd / NC-51 N** via **EXIT 64A** toward **Matthews**.	**Go 0.6 Mi**	20.1 mi
	8. Turn **left** onto **Park Rd**. *Firehouse Subs is on the corner* *If you reach Park Cedar Dr you've gone about 0.3 miles too far*	**Go 0.1 Mi**	20.2 mi
	9. **10628 PARK RD** is on the **left**. *If you reach Willow Ridge Rd you've gone about 0.2 miles too far*		20.2 mi
	10628 Park Rd Charlotte, NC 28210-8407	**20.2 mi**	**20.2 mi**

Total Travel Estimate: **20.23 miles - about 28 minutes**

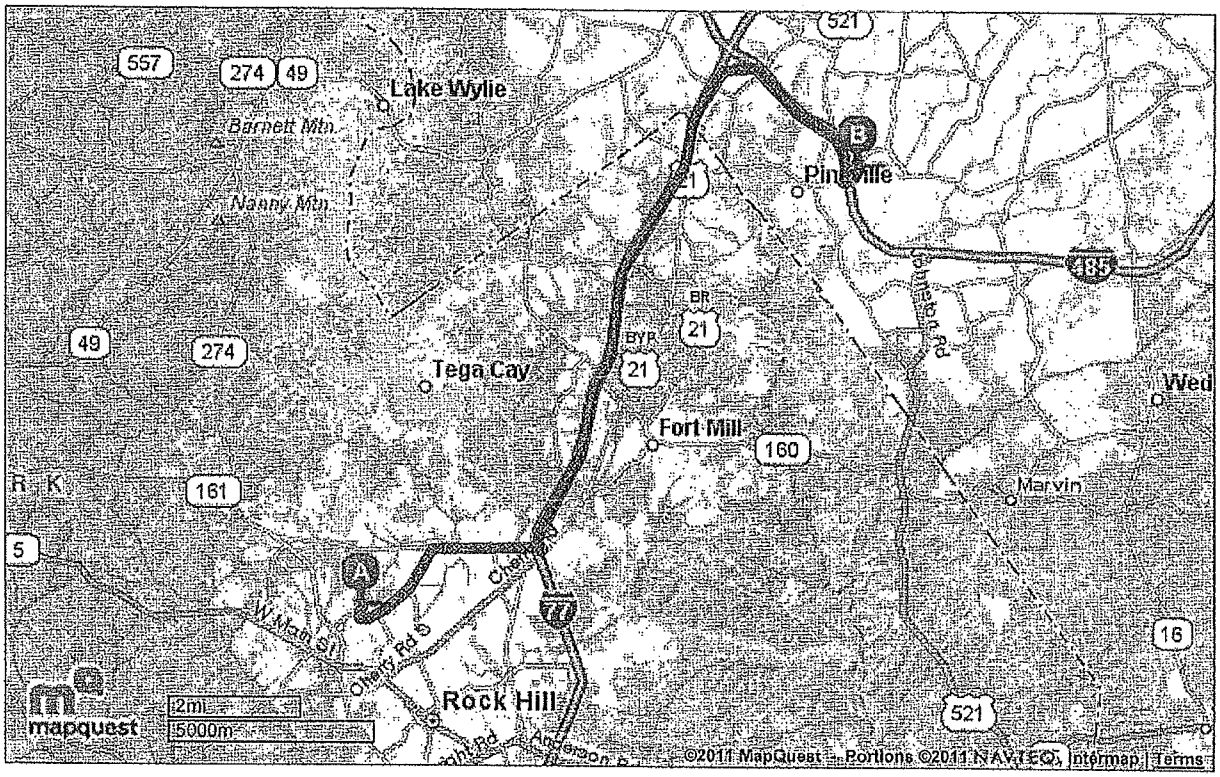

Exhibit B

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	February 27, 2007
FINDINGS DATE:	March 2, 2007
PROJECT ANALYST:	Carol L. Hutchison
CHIEF:	Lee B. Hoffman

PROJECT I.D. NUMBERS: F-7706-06/ The Charlotte-Mecklenburg Hospital Authority and Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center – Union/ Develop a healthplex (i.e., freestanding emergency room with outpatient imaging and diagnostic services) in Waxhaw, which will be licensed as part of Carolinas Medical Center–Union/ Union County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

The applicants do not propose an increase in the number of licensed beds, operating rooms or GI endoscopy rooms located in Union County. Further, the applicants do not propose to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the *2006 State Medical Facilities Plan (2006 SMFP)*. Therefore, there are no need determinations that are applicable to the project. Additionally, there are no policies in the *2006 SMFP* that are applicable to the proposed project. Thus, this criterion is not applicable to the proposed project.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial

and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The Charlotte-Mecklenburg Hospital Authority (CMHA) and Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union (CMC-Union) propose to develop Carolinas Medical Center-Union Healthplex (CMC-Union Healthplex) at the intersection of Providence Road (Highway 16) and Gray Byrum Road, to be licensed as part of CMC-Union. Based on the representations in Section II.1, pages 32-39, the design schematic provided in Exhibit 3, and the list of equipment to be acquired provided in Exhibit 28, the applicants propose to offer the following services at the healthplex:

- a new 24 hour freestanding emergency department with 8 treatment rooms
- 3 new unlicensed observation beds
- new laboratory
- new pharmacy (through a Pyxis MedStation unit) [1]
- 2 new fixed x-ray machines
- 1 new portable x-ray machine
- 1 new mini C-arm
- 1 new portable fluoroscopy unit
- pad for operation of an existing mobile MRI unit (through contract with Carolinas Imaging Services)
- 1 new 64-slice CT scanner
- 1 new ultrasound unit

POPULATION TO BE SERVED

The following table illustrates the projected patient origin for CMC-Union Healthplex by service type in the third operating year, as reported by the applicants in Exhibits 16 and 17.

	% OF TOTAL PATIENTS BY SERVICE			
COUNTY	ED	OBSERVATION	IMAGING SERVICES	LAB
Mecklenburg	9.0	9.0	9.0	9.0
Union	70.6	76.9	70.6	71.0
York, SC	19.1	12.9	19.1	19.0
Lancaster, SC	1.3	1.3	1.3	1.0
Total [1]	100.0%	100.1%	100.0%	100.0%

[1] May not equal 100% due to rounding.

[1] According to information obtained from the WEB, the Pyxis MedStation functions *"like an ATM with PIN-controlled access, the system delivers precise amounts of prescribed drugs for administration by caregivers to patients."*

In Section III.5(a), pages 135-136, the applicants state

> *"...the primary service area consists of census tracts 210.01, 210.02, 210.03, 209.02, and 112 (South Carolina) in their entirety. The secondary service area consists of contiguous areas primarily within a ten mile radius, with the exception* [sic] *particularly sparsely populated areas."*

The applicants state the secondary service area consists of census tracts in Union County (NC), Mecklenburg County (NC), York County (SC), and Lancaster County (SC). See service area map on page 88 of the application. On page 82 of the application the applicants state *"...CMC-Union projects 80 percent of its patient population to originate from the proposed* [primary] *service area (less than four zip codes) and the remaining 20 percent to originate from contiguous areas within a ten to fifteen mile radius of the proposed site."*

The primary service area consists of three census tracts in Union County (NC), and a fourth census tract (112) located in the northern panhandle of Lancaster County, South Carolina. In the tables in Exhibit 16 it appears, the applicants assign census tract 112 to York County for the purpose of defining the patient origin for the primary service area. However, census tract 112 is located in Lancaster County, not York County. Thus, a projection of only 1% of patients originating from Lancaster County and 19% from York County is questionable. See additional discussion of inconsistent representations regarding the service area in the analysis of ED utilization.

Therefore, the applicants did not adequately identify the population they propose to serve.

ANALYSIS OF NEED FOR THE PROPOSED SERVICES

In Section III.1(a), the applicants state

> *"In evaluating the health care needs of the Waxhaw/Weddington community in southwest Union County, CMC-Union examined a number of factors. CMC-Union examined the capacity of existing facilities with respect to emergency services, as well as the outpatient service utilization trends in these facilities. In addition, CMC-Union sought to determine the accessibility of existing health care resources in Union County by looking at the distance that Waxhaw residents currently must drive in order to access health care resources in the area. CHS also evaluated population growth in Waxhaw to further demonstrate the need to locate additional health care services, namely, those included in the proposed healthplex, in Waxhaw.*
>
> ...
>
> *Emergency departments surrounding the service area are experiencing utilization trends similar to those experienced nation-wide. Population*

growth, coupled with increased use rates, are straining the existing system of emergency care.

...

The American College of Emergency Physicians recommends that emergency department exam room capacity is 1,500-2,000 visits per year. ...[A]ll CHS's Mecklenburg facilities, are operating above this recommended capacity level, thus indicating that existing capacity is not meeting the need of the population. Based on current utilization, and applying the high range of the industry standard, the system currently needs fifteen additional rooms.

CHS evaluated growth trends in the emergency departments at CMC-Union and CHS's Mecklenburg County facilities to determine the system-wide need for additional capacity in the future.

...

In order to calculate projected utilization, CHS examined the historical growth rate in each of its Mecklenburg County facilities as well as CMC-Union. Based on the calculated compound annual growth rate (5.2 percent in CHS's Mecklenburg County facilities and 3.5 percent in CMC-Union) CHS projected emergency department utilization in each of its facilities and system wide.

...

CHS Mecklenburg County facilities are expected to have an additional 140,017 emergency department visits by 2012. With a total of 354,378 visits projected for 2012, the CHS Mecklenburg County facilities will need 63 additional rooms for a Mecklenburg Area Total of 177. In addition, CMC-Union will need an additional eight rooms, for a total of 27.

Other hospitals in the Charlotte metropolitan area are experiencing similar growth trends. CHS examined utilization from the Novant/Presbyterian hospitals in Charlotte and found a similar growth trend. While the number of emergency department rooms is not publicly available, actions taken by the Novant/Presbyterian system, such as the recent emergency department expansion at Presbyterian Hospital Matthews, indicate that it is also facing increasing utilization.

...

CMC-Union examined trends In [sic] *addition to historical data for the proposed service area. Specifically, CMC-Union examined trends in patient care at CMC-Union, in addition to two other representative community hospitals in the region: CMC-University and CMC-Pineville. CMC-Union believes that these hospitals have a patient population representative of that of the proposed healthplex. This analysis demonstrates than an extremely high percentage of patients treated in acute care hospitals are outpatients. ...*

...

...nationwide trends in outpatient care are present in the Mecklenburg County/Union region. ... at most 7.7 percent of patients at an area community hospital require an overnight stay.

...

The projected area population statistics are derived from Metrostudy, a national residential real estate advisory service specializing in the single-family home construction industry. These statistics are compiled on a quarterly basis through comprehensive on-site surveys of developments. The population statistics are derived from two key data sets - (1) Metrostudy - adjusted 2006 population, and (2) current developments and future residential growth opportunity (total occupied units, current housing inventory, vacant developed lots, and lots for future development. [sic] *The specific methodologies underlying these data sets and their use in developing population data for 2006 to 2011 are detailed in Section III.1(b).*

The service area for the proposed project contains areas of rapid population growth, housing development, business development and transportation improvements.

...

Not only will the healthplex be utilized by the currently sustained population, but also by the growing influx of new citizens. ...These newcomers are a major reason that housing developments are filling rapidly and continuing to be built. In 2005, 38 percent of homes sold were to newcomers and Union County joined Mecklenburg County among the nation's top growing markets.

...

Census Tract 210.01 – Northwest Union County

The proposed site is at the southern tip of census tract 210.01 (Northwest Union County), which is by far the most dense population center in the defined service area, having experienced over 15 percent annual population growth from 2000-2005. This census tract encompasses the towns of Weddington and Marvin, with Wesley Chapel at the western edge. Northwest Union County's explosive population growth has been driven by the following:

- *Spillover of southern Mecklenburg County growth as available land in Mecklenburg is absorbed by development*
- *Completion of the southern leg of I-485 in 2002, providing direct access to the Charlotte Douglas International Airport.*
- *Extension of Rea Road into Union County in 2002. In 1990, the population at this exit was 1,800 and in 2005 there are now 11,000 persons in a one mile radius.*

Development in this area has been heavy along Highway 16 (Providence Road), which extends from downtown Charlotte through Union County. ...Northwest Union County is traversed by Marvin Road/New Town Road, which connects to Highway 521 running through the northern tip of Lancaster County, and by Highway 84, which intersects Highway 16 and runs westward to Monroe.

...

Census Tracts 210.03/209.02 Mineral Springs & Jackson Township

The proposed site is just west of census tract 210.03, which includes the town of Mineral Springs. SR-75 (Waxhaw Highway) cuts across the area connecting to US-521 (Charlotte Highway) and SR-84 (Weddington Road) in Monroe. Historical growth in this area has been modest, but large developments will initiate greater population density. ...Census Tract 209.02 contains the Union County township of Jackson. This census tract has seen the slowest population growth out of the service area at 1 percent from 2000-2005. Growth will be driven by:

- *Availability of expansive land*
- *Proximity to Monroe and Waxhaw with access to interstate corridors*
- *Property tax rate at a low $.0027 for every $100.*

Census Tract 201.02 – Waxhaw

The project site is on the top border of census tract 201.02, slightly more than two miles north of the town of Waxhaw. ...This area has grown 6.3 percent from 2000-2005. Growth will be driven by:

- *While many citizens hope to preserve the small businesses, they are experiencing a major construction boom with big business becoming attracted to the area*
- *Area offers access to the I-485 linking to two Interstate Highways and other major highways*
- *Ease in transportation to include developer paid $1.5 million bridge construction and widening of N.C. 16. The connection of Cuthberton Road to Kensington Road allows better town access as an alternative route from N.C. 16 around Waxhaw.*

...

Census Tract 112 – Northern Lancaster Panhandle

The proposed healthplex is bordered to the west by northern Lancaster County. Census Tract 112 has grown 7.5 percent annually since 2000 and is paced for tremendous population growth in the next five to ten years. In fact, The Charlotte Observer recently reported that 'within a

few years the county's northern panhandle will swell to five times its 2000 census population of 7,059 people.'"

...

...Further, support for the proposed healthplex comes from the following:

- *Population growth in the region indicates need for additional health care resources in the future;*
- *Development in and around the Charlotte/Mecklenburg area is resulting in highly congested traffic in primary corridors, specifically Providence Road, extending from Waxhaw to existing CHS facilities;*
- *Outpatient utilization trend in the region indicates demand for increased access to outpatient health care services; and*
- *Emergency departments in Mecklenburg/Union County area are currently operating at or above capacity levels, therefore indicating a need for additional capacity located close to the residents of Waxhaw."*

The following table illustrates projected utilization of services provided at CMC-Union Healthplex during the first three operating years, as reported by the applicants in Section IV.2, page 149a.

	YEAR 1 (1/3/09 - 1/2/10)	YEAR 2 (1/3/10 - 1/2/11)	YEAR 3 (1/3/11 - 1/2/12)
ED Visits	5,143	7,792	10,692
Observation Patients	357	624	870
MRI	680	1,011	1,364
CT scans	2,268	3,383	4,575
US procedures	873	1,289	1,728
X-ray procedures	4,228	6,295	8,505
Lab tests	41,620	62,376	84,758

In Section III.1(b), pages 104-136, the applicants describe the assumptions and methodologies used to project utilization of the proposed healthplex as follows:

"To project utilization for the Emergency Department (ED), CMC-Union used the following methodology, applied to the service area population:

1. *Calculate historical zip-code based use rates and convert to census tract-based use rates*
2. *Project future use rates.*
3. *Determine total service area market demand.*
4. *Determine market share for the proposed healthplex.*
5. *Calculate total volume for the proposed healthplex.*

...

Methodology 1: Emergency Department

CMC-Union used 'Methodology I,' as described above, in developing utilization projections for the Emergency Department. In obtaining historical market volume for emergency department visits, CMC-Union used Solucient Inpatient Discharge and Emergency Department Visit databases. Inconsistencies in the data from 2003 and 2004 led to the decision to only use 2005 data in the projections. ED use rates were first calculated using the following methodology. Use rates for census tracts 210.01, 210.02, 210.03 and 209.02 are based upon CY2005 actual ED visits use rates per 1000 (Solucinet [sic] *Inpatient Discharge and Emergency Department databases) for zip codes 28173, 28104 and 28112. The geographic areas of the census tracts and zip codes were overlayed to estimate the portions of each zip code to be assigned to each census tract. The resulting division among each census tract is shown in the table below.*

Weighted Average %	28173	28104	28112
210.01	81%	19%	0%
210.02	100%	0%	0%
210.03	30%	0%	70%
209.02	28%	0%	72%

The use rate for census tract 112, in Lancaster County, SC is based upon the overall Lancaster County ED use rate per 1000 population from the South Carolina Office of Research and Statistics. Use rates for census tracts 210.01 and 210.02 were increased by five percent annually to more closely approximate the remainder of the service area. Currently, ED visit use rates are extremely low for zip codes 28173 and 28104. As these areas experience more rapid and diverse population growth, as well as receiving more rapid access to emergency care, it is anticipated that the ED visit use rates will increase.

According to the National Center for Health Statistics (NCHS), CMC-Union's method of projecting use rates forward is conservative. NCHS' latest study on emergency departments came to the following conclusion regarding use rates: 'From 1994 through 2004, the overall ED utilization rate increased by six percent, from 36.0 to 38.2 visits per 100 persons.' The 2004 national use rate, which is continuing to rise, is higher than all projected use rates for the healthplex service area. The overall calculated 2005 use rate for the market is only 267 visits per 1,000 persons (or 26.7 per 100 persons), further demonstrating the conservative nature of CMC-Union's projections.

...

By applying the projected use rates to the projected population, CMC-Union calculated the total projected market volume for the service area.

Next, CMC-Union applied market share assumptions for each census tract to determine the total number of healthplex service area visits. The market shares assumptions for CMC-Union Healthplex were based on proximity and accessibility to alternate providers in comparison to CMC-Union Healthplex. The largest market share percentage [35%] *is expected to originate from census tract 210.02 primarily due to its current distance from providers. CMC-Union Healthplex is only expected to capture 20 percent of census tract 210.03 due to its proximity to CMC-Union. A 25 percent market share is assumed for the remaining census tracts. CMC-Union Healthplex believes these assumptions are extremely conservative in nature, as patients prefer nearby treatment which the proposed healthplex will provide to the entire service area.*

For the first two project years, the market share was adjusted down to 60 percent and 80 percent of the projected total market share, respectively, to account for a ramp-up period for the new healthplex.

However, the applicants' market share projections in the narrative above do not correlate to the applicants' projections as shown in the table below from page 112 of the application. For example, in the third year after project completion, CMC-Union Healthplex is expected to capture 25% of census tract 210.03 instead of 20%, and a market share of 30% is assumed for census tract 210.01, not 25% as stated by the applicants.

Market Share Assumptions	PY 1	PY 2	PY 3	PY 4
210.01	18.0%	24.0%	30.0%	30.0%
210.02	21.0%	28.0%	35.0%	35.0%
210.03	15.0%	20.0%	25.0%	25.0%
209.02	15.0%	20.0%	25.0%	25.0%
112	15.0%	20.0%	25.0%	25.0%

Next, the projected service area visits by census tract were multiplied by each respective healthplex market share. Resulting is [sic] *the projected annual number of service area visits at the proposed healthplex.*

The resulting number of healthplex visits is shown in the table below.

Total Visits	PY1	PY2	PY3	PY4
Primary Service Area Visits (80%)	4,114	6,234	8,553	9,674
Secondary Service Area Visits (20%)	1,029	1,558	2,138	2,419
Healthplex Total Visits	5,143	7,792	10,692	12,093

Using the total projected number of visits, CMC-Union determined the number of emergency department visits per treatment room, based on the

proposed eight ED beds. The resulting numbers are shown in the table below.

ED Visits / Treatment Room	PY1	PY2	PY3	PY4
Total Healthplex Visits	5,143	7,792	10,692	12,093
ED Treatment Rooms	8	8	8	8
Visits per Room	643	974	1,336	1,512

Industry standards for the number of emergency visits per treatment station vary from 1,500 visits per year to around 2,000 visits, depending on patient acuity, level of care provided, and other factors. A 2002 report from the American College of Emergency Physicians recommends 1,500 annual visits per emergency department room; however, CMC-Union recognizes the varying reports on ED capacity and remains conservative in its assumption of 1,500 to 2,000. The assumption of 1,500 to 2,000 visits per year as capacity gives the proposed healthplex a capacity between 12,000 and 16,000 with eight treatment areas. As shown in the table above, CMC-Union does not project its treatment rooms to achieve 1,500 visits each until the fourth project year. However, if 1,500 visits is assumed to be the capacity, CMC-Union Healthplex will be operating at 89 percent occupancy by the third year, and will exceed the 1,500 visits by the fourth project year.

Methodology 2: Observation Beds

To project utilization for observation beds, CMC-Union used the following methodology, applied to the service area population:

1. *Obtain historical service area volume for CHS facilities within Mecklenburg and Union counties (other provider data is not available for this service).*
2. *Calculate historical capture rates.*
3. *Project future capture rates.*
4. *Determine total CHS facility patients within the service area.*
5. *Project internal volume shifts for CMC-Union Healthplex.*
6. *Calculate total volume for CMC-Union Healthplex.*

...

CMC-Union used 'Methodology 2,' as described above, in making utilization projections for observation beds. In obtaining historical capture rates for observation patients, CMC-Union used 2005 internal (Trendstar) data for CHS facilities in Mecklenburg and CMC-Union. Use rates were calculated for zip codes 28104, 28173, 28112, and

29715. To convert the zip code capture rates into service area capture rates, the geographic areas of the census tracts and zip codes were overlayed to estimate the portions of each zip code to be assigned to each census tract.

...

The total market demand from CHS facilities for the service area was determined by multiplying the projected capture rates by the projected population, as described previously. The resulting number of service area visits is shown in the table below.

CHS Facility, Primary Service Area Observation Patients	PY 1	PY 2	PY 3
210.01	405	438	511
210.02	172	177	187
210.03	227	264	358
209.02	148	150	154
112	183	219	182
Total	1,135	1,248	1,392

Next, CMC-Union applied internal volume shift assumptions for each census tract to determine the total healthplex service area visits. CMC-Union assumes a large portion of the service area shift will originate from CHS facilities, therefore, 50 percent market shift from CHS facilities in the service area was assumed.

The projected internal volume shift for CMC-Union Healthplex, as calculated above, was assumed to be achieved by the third project year. For the first two project years, the shift was adjusted down to 60 percent and 80 percent of the projected total volume shift, respectively, to account for a ramp-up period for the new healthplex. ...

...

As stated previously, the total projected market volumes by census tract were multiplied by their respective shift percentages to determine the total healthplex service area volume .... The total market volumes only include CHS facilities,...

...

In addition to the projected visits from the service area, CMC-Union assumes that 20 percent of its patients will originate from outside the limited service area, primarily from the communities bordering the proposed service area. This number is used in calculating the total number of healthplex patients for the proposed project years.

...

The resulting number of healthplex visits is shown in the table below.

Total Observation Patients	PY1	PY2	PY3
Primary Service Area Visits (80%)	286	499	696
Secondary Service Area (20%)	71	125	174
Healthplex Total Visits	357	624	870

The total number of observation patients was divided by the number of proposed observation beds (three) and again by 365 days to determine the number of patients per bed per day. CMC-Union uses the assumption that each observation bed can serve one patient per day. Since observation bed use is not to exceed 24 hours per patient, it is reasonable to assume no more than one patient will occupy each bed per day, due to availability of other beds and turnover. With this assumption, the number of patients per bed per day is also an occupancy percentage, resulting in 73 percent occupancy by the third project year. A summary of the above calculations are (sic) *shown in the table below.*

...

Observation	PY1	PY2	PY3
Observation Patients	357	624	870
Observation Beds	3	3	3
Occupancy	32.6%	57.0%	79.4%

Methodology 3: Imaging Services

To project utilization for MRI, CT, Ultrasound, and X-ray services, CMC-Union used the following methodology:

1. Obtain outpatient service area volume from Medstat for appropriate zip codes

2005 and 2010 estimated service area outpatient volume was obtained using Medstat. Medstat is a respected nationwide expert in health care data and information. CMC-Union chose this vendor specifically because of its expertise in projecting health care utilization trends. Medstat projected the use rate for the various procedures based on data collected from numerous sources, as well as projections for increases in the use of each technology; it then applied these use rates to projected population data to determine the projected number of procedures in each zip code. Volume resulting from physician offices was excluded, as there will likely be little shift in volume from physician offices. Projected volume for years 2006 to 2009, along with 2011, was calculated by using the compound annual growth rate from 2005 to 2010. The

service area includes zip codes 28104, 28173, 28112, and 29715.

2. Calculate use rates for each zip code.

Use rates were calculated by dividing the outpatient volume by the total population for each corresponding zip code. To determine the historical and projected populations for each of the zip codes, CMC-Union obtained the most recent population data available from Claritas. Because Claritas provides population statistics in five-year increments, CMC-Union used the compound annual growth rate (CAGR) from 2000-2006 to calculate the zip code populations for the years 2001-2005, and the CAGR from 2006-2011 was used in projecting populations for the years 2007-2010. ...Annual population statistics are provided as part of the utilization methodologies for the individual services in Exhibit 15.

3. Convert zip code use rates into census tract use rates.

To convert the zip code use rates into service area use rates, the geographic areas of the census tracts and zip codes were overlayed to estimate the portions of each zip code to be assigned to each census tract.

4. Calculate total service area volume.

Service area volume was calculated by multiplying the census tract use rates by their respective census tract populations.

5. Apply historical CMC-Pineville outpatient market share percentages.

CMC-Union considered using its own market share data to determine market share for the proposed healthplex. However, CMC-Union is the sole provider in Union County; thus its market share is relatively high compared to providers in other areas of the region. ...CMC-Pineville's market share was the lowest among the compared facilities; therefore, CMC-Union conservatively chose to use its market share for CMC-Union Healthplex.

CMC-Pineville market share was obtained by dividing 2005 historical outpatient volumes for a four zip-code service area (internal data) by the total outpatient volume, excluding physician offices, for the same service area. The four zip-code service area for CMC-Pineville consists of zip codes

28227, 28210, 28226, and 29715. [Note: These are not the zip codes for CMC-Union Healthplex]

...

By multiplying the total service area volume for the proposed healthplex by the market share, the total service area volume for the proposed healthplex is calculated.

...

6. Apply ramp-up percentages for the first three project years.

The project year volume for the proposed healthplex, as calculated above, was assumed to be achieved by the third project year. For the first two project years, the volume was adjusted down to 60 percent and 80 percent of the projected total volume, respectively, to account for a ramp-up period for the new healthplex.

7. Add 20 percent inmigration to the service area volumes.

In addition to the projected volume from the four-zip code [primary] *service area, CMC-Union assumes that 20 percent of its volume will originate from the secondary service area, as discussed previously. This number is used in calculating the total volume for CMC-Union Healthplex. ...*

...

Total MRI Volume	*2009*	*2010*	*2011*
Primary Service Area (80%)	*544*	*809*	*1,091*
Secondary Service Area (20%)	*136*	*202*	*273*
CMC-Union Healthplex Volume	***680***	***1,011***	***1,364***

Total CT Volume	*2009*	*2010*	*2011*
Primary Service Area (80%)	*1,814*	*2,707*	*3,660*
Secondary Service Area (20%)	*454*	*677*	*915*
CMC-Union Healthplex Volume	***2,268***	***3,383***	***4,575***

Total Ultrasound Volume	*2009*	*2010*	*2011*
Primary Service Area (80%)	*699*	*1,031*	*1,383*
Secondary Service Area (20%)	*175*	*258*	*346*
CMC-Union Healthplex Volume	*873*	*1,289*	*1,728*

Total X-ray Volume	*2009*	*2010*	*2011*
Primary Service Area (80%)	*3,382*	*5,036*	*6,804*
Secondary Service Area (20%)	*846*	*1259*	*1701*
CMC-Union Healthplex Volume	*4,228*	*6,295*	*8,505*

...

Methodology 4: Laboratory

Projections for laboratory (lab) volume were made using a ratio of laboratory tests to the combined ED and imaging volume. A combined ED and imaging volume was used since these services generate the need for laboratory services. This ratio was calculated using historical service area volume from all CHS facilities located in Mecklenburg County plus CMC-Union. This data was obtained using internal data (Trendstar) for imaging services, excluding emergency department and surgery, and the Solucient Inpatient Discharge Database and Emergency Department Database for emergency services. The calculations made in determining the ratio are shown in the table below.

...

Laboratory Ratio Calculation	**2005**
MRI	1,035
CT	2,069
Ultrasound	1,409
X-ray	2,374
ED	8,670
Total	15,558
Lab	49,085
Ratio (Lab/Total)	**316%**

Next, the calculated ratio was applied to the total volume for imaging and emergency service combined, as calculated previously, to determine the total laboratory volume for the proposed healthplex. The following table shows the calculations made in the process and the resulting volume.

Laboratory	PY1 2009	PY2 2010	PY3 2011
MRI	680	1,011	1,364
CT	2,268	3,383	4,575
Ultrasound	873	1,289	1,728
X-ray	4,228	6,295	8,505
ED	5,143	7,792	10,692
Total	13,192	19,770	26,864
Ratio	316%	316%	316%
Total Laboratory Volume	**41,620**	**62,376**	**84,758**

Analysis of Projected ED Utilization

The project analyst determined the applicants overestimated the number of emergency department visits to be provided. Specifically, the applicants calculated ED use rates based on emergency room visits to inpatient facilities, instead of those appropriate for treatment in a remote freestanding outpatient emergency department, without operating rooms. For example, the applicants made no estimated adjustment to the ED use rate for trauma patients who will continue to be taken to Carolinas Medical Center or CMC-Union by EMS. In fact, on pages 32-33, the applicants state *"While CMC-Union Healthplex does not expect to receive trauma patients from EMS, it is well aware that many trauma patients arrive as walk-ins. Trauma such a gun-shot wounds, myocardial infarctions, strokes and other critical cases arriving as ambulatory patients must be stabilized and transferred to a higher level of care."*

In addition, in the methodology for the ED utilization projections, the applicants did not take into consideration patients that will choose to use the two urgent care centers owned by CHS which are located in the proposed secondary service area (Carolinas HealthCare Urgent Care – Union West in Indian Trail, NC and Carolinas HealthCare Urgent Care-Ballantyne in Charlotte), instead of the proposed healthplex.

Further, the applicants calculated ED use rates for each census tract in the primary service area (census tracts 210.01, 210.02, 210.03, 209.02 and 112). The applicants state they increased the use rates for census tracts 210.01 and 210.02 by five percent annually from year 2005 through to year 2012 and held the remaining three census tract use rates constant, as shown in the following table.

Use Rates per 1,000	2008	2009	2010	2011	2012
210.01	221	269	282	296	311
210.02	224	272	286	300	315
210.03	313	313	313	313	313
209.02	316	316	316	316	316
112	368	368	368	368	368
Total	267	301	311	315	324

*See census tract area map on page 88 of application

The reason given by the applicants for increasing use rates for census tracts 210.01 and 210.02 by 5% annually was to make them more comparable to the higher use rates calculated for 210.03, 209.02 and 112. Also, the applicants note the National Center for Health Statistics (NCHS) reported the national 2004 ED use rate as 38.2 visits per 100 persons, or 382 visits per 1,000 persons. However, the national use rate includes ED visits of all levels of acuity, for all regions of the country (e.g., metropolitan, nonmetropolitan), and for all socioeconomic conditions. Further, NCHS determined the national average ED use rate grew by 6% over a ten year period (1994 – 2004), or about 0.60% per year. The applicants state on page 110 *"According to the National Center for Health Statistics (NCHS), CMC-Union's method of projecting use rates forward is conservative."* However, the applicants did not demonstrate the proposed 5% annual increase in projected ED use rates in the two zip code areas is "conservative" in comparison to only a 0.6% annual national average increase in ED use rate. Thus, the applicants' justification of the projected ED use rate for these two zip code areas is unreasonable.

Further, the applicants provided inconsistent information regarding the primary and secondary service areas. The applicants state the primary service area is five census tracts as explained on page 79 and shown on page 80. On page 108, the applicants allocated 100% of census tract 112 to Zip Code 29715, although census tract 112 falls in both zip code 29720 and 29715. Also, on page 137 the applicants state "*Census tracts 210.01, 210.02, 210.03, and 209.02 are all in Union County, while census tract 112 is in York County, South Carolina.*" Exhibit 16 also shows the primary service area includes York County not Lancaster County. However, based on the map on page 88 and the description on pages 99-103, census tract 112 is actually in Lancaster County and the census tracts in York County are in the applicants' secondary service area.

The applicants also state "*CHS hospitals provide the second-highest level of inpatient discharges to residents of York County and have a substantially stronger presence in Northern York County. ...A significant portion of the patients to be served by the proposed hospital* [Fort Mill, SC] *are currently treated at Carolinas Medical Center, CMC-Pineville and CMC-Mercy.*" (South Carolina Department of Health and Environmental Control *Project*

Review Write-Up on Carolinas Medical Center – Fort Mill CON Application, pages 4 & 7). Therefore, the applicants are not clear whether the primary service area includes York County or Lancaster County.

Additionally, the ED use rate for census tract 112 was based on the ED use rate for all of Lancaster County. However, the northern panhandle of Lancaster County only includes a small geographic portion of the county and does not include the cities of Lancaster and Kershaw. Further, the applicants did not demonstrate why the northern panhandle of Lancaster County would have the same ED use rate as the rest of the county, as opposed to York County which is adjacent to census tract 112. In fact, the ED use rate for York County is significantly lower than the ED use rate for Lancaster County. According to the South Carolina Office of Research & Statistics, the 2004 ED use rate for Lancaster County was 368 per 1,000 persons, while it was only 220 per 1,000 persons for York County. Therefore, if the ED use rate for census tract 112 were recalculated using the York County ED use rate in lieu of the Lancaster County rate, the result would be significantly fewer patients to be served by the proposed healthplex ED.

In addition, the applicants' projection that 20 percent of ED patients served at the healthplex would come from the secondary service area (2138 visits) in Project Year 3 (FY 2011) is also questionable. Patient origin for the secondary service area is broken out in Exhibit 16 as 44.80% Mecklenburg County (957 visits), 36.5% Union County (780 visits), 12.3% York County, SC (263 visits) and 6.4% Lancaster County, SC (138 visits). As shown by the service area map on page 87, the portion of Mecklenburg County encircled and color coded as the secondary service area includes only a very small area located between CMC-Pineville and Presbyterian Hospital – Matthews. It is doubtful that a higher number of ED patients will travel south from this area of Mecklenburg County to the healthplex in Union County, than from the remaining areas of Union County, when there is at least one other facility in close proximity. Further, the projection of Union County patients from the secondary service area appears high given the proximity of these census tracts to CMC-Union and Presbyterian Hospital-Matthews.

Also, the projection of patients from the applicants' inclusion of census tract 209.02, which extends beyond the 10 mile radius, is questionable since the major thorough fares crossing the census tract extend northwest to Monroe and southeast to Lancaster in SC, and away from the northwestern direction of Waxhaw. Moreover, in May 2006, the South Carolina Department of Health and Environmental Control approved Fort Mill Medical Center which will provide 24-hour emergency room service and would reduce the number of South Carolina residents likely to seek ED services in Union County.

Further, on page 73, the applicants discuss CMC-Union's and CHS's Mecklenburg County hospital emergency departments in terms of population

growth, capacity, and increased use rates, which are *"straining the existing system of emergency care. ...CHS therefore believes that additional emergency department capacity is essential to support the growing population in the region."* However, the table below presents the number of ED treatment rooms approved or pending for the facilities located within a 20 mile drive from Waxhaw.

Facility	Existing ED Treatment Rooms*	Approved or Pending New ED Treatment Rooms**	Total ED Treatment Rooms
CMC-Union	19	--	19
CMC-Pineville	21	+12	33
Presbyterian-Matthews	18	+15	33
Total	58	+27	85

*Project I.D. #F-6821-03 & #F-7198-05 (Presbyterian Hospital-Matthews); Project I.D. #F-7313-05 (CMC-Pineville); and Project I.D. #F-7706-06 page 73, for CMC-Union
**CON approved 4/05 for Presbyterian Hospital-Matthews and CON approved 12/06 for CMC-Pineville.

As shown in the table above, there are three existing hospitals with 24-hour emergency departments within 20 miles of the proposed facility – CMC-Union, CMC-Pineville, and Presbyterian Hospital-Matthews. Of note, CMC-Pineville in Project I.D. #F7313-05 cited growth in the Waxhaw and Fort Mill areas as evidence of the need to add 12 additional ED treatment rooms. Also, in Project I.D. #F-6821-03 Presbyterian Hospital-Matthews cited escalating ED volumes, high ED use rates and population growth in its primary and secondary service areas, both of which included Union County (25.25% of PHM's ED Patient Origin in 2002).

With regard to ED services at CMC-Union, the applicants state on page 114,

> *"CMC-Union's emergency department has experienced increasing utilization over the past several years and will soon need to expand. While the proposed project will not alleviate the need for this expansion, it will provide resident* [sic] *of the proposed service area with a local option for emergency care."* (Page 114).

Thus, it appears that the applicants also propose to expand ED services at CMC-Union even if the healthplex is approved. Therefore, the applicants did not adequately demonstrate the need for the development of ED services they propose to provide in Waxhaw in addition to the expansions of the existing facilities.

Analysis of Observation Beds

In Methodology 2, the applicants used the historical utilization of observation beds at CMC-Union and CHS facilities in Mecklenburg County, by residents

of zip codes 28104, 28173, 28112, and 29715, to calculate historical and projected observation bed use rates. However, the applicants failed to explain why the utilization of observation beds in urban area acute care hospitals, with surgical and medical services and EDs capable of providing all levels of acuity, would be comparable to the more limited services of a freestanding outpatient healthplex without surgical capabilities. Also, the applicants estimated the observation bed use rate for census tract 112 was based on utilization for all of zip code 29715 (York and Lancaster Counties), which is inconsistent with the applicants' use of only Lancaster County for determining ED use rates. Moreover, the applicants omitted discussion of the types of patient diagnosis expected to use the observation beds, and the prevalence of disease in the proposed service area that would support the need for these beds. Also, the applicants assumed a 50% market shift in observation bed utilization from CHS hospitals in the service area to the healthplex, but failed to demonstrate the reasonableness of the shift from the CHS facilities, given the differences in the levels of care. The applicants also did not identify the specific facilities from which patients would shift or the number of patients to be shifted from each facility.

Further, utilization of observation beds will be based primarily on patients seeking ED services at the facility. Therefore, because the projected number of ED visits is unreasonably high, the number of observation patients to be served is also unreasonably high for the same reasons.

Analysis of Imaging Services

The applicants state on page 138 "*CMC-Union used the same patient origin percentages for imaging services as were calculated with the emergency department. Although CMC-Union Healthplex will have outpatient services, the majority of imaging volume will result from ED patients; therefore, the same patient origin is expected.*" Conversely, in Exhibit 15 and on page 121, the applicants calculated the healthplex's projected market share for MRI, CT, Ultrasound and X-ray services based on CMC-Pineville's market share in its four zip code service area (28227, 28210, 28226 and 29715). Therefore, the methodology used to project imaging volume was not the same methodology as the methodology used to project the ED utilization projected for the healthplex. Therefore, the applicants provided inconsistent statements regarding the basis for their projections. Further, because the applicants state the majority of imaging volume will come from ED patients and the projected number of ED procedures is unreasonably high, then the number of imaging procedures is also unreasonably high for the same reasons.

Analysis of Laboratory Volume

On page 126 the applicants state "*Projections for laboratory (lab) volume were made using a ratio of laboratory tests to the combined ED and imaging*

volume. A combined ED and imaging volume was used since these services generate the need for laboratory services." As discussed above, since ED and imaging services volumes were based on unreasonable assumptions and projections, projected laboratory volumes are also unreasonable.

In summary, the applicants did not adequately identify the population proposed to be served and did not adequately demonstrate the need for the proposed project. Therefore, the application is nonconforming with this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

CMC-Union Healthplex does not propose to reduce, eliminate or relocate any existing services.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

CMC-Union Healthplex – In Section II.5, pages 42-44, the applicants discussed several alternatives they considered prior to submission of this application. However, the application is not conforming to all applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (12), (18a) and *10A NCAC 14C .2300 – Criteria and Standards for Computed Tomography Equipment.* Therefore, the applicants did not adequately demonstrate that the proposal is an effective alternative and the application is nonconforming to this criterion. Consequently, the application is disapproved.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

NC

In Section VIII.1, page 181, the applicants project that the total capital cost of the project will be $19,392,000 as illustrated below. The Charlotte-Mecklenburg Hospital Authority (CMHA) is purchasing the land at $2,200,000 and CMC-Union is funding the remaining capital costs ($17,192,165).

Site Costs		
Purchase Price of the Land	$2,200,000	
Site Preparation Costs	$1,383,400	
Subtotal Site Costs		$3,583,400
Construction Costs		$6,358,420
Miscellaneous Costs		
Fixed Equipment	$2,271,000	
Movable Equipment	$4,919,580	
Furniture	$299,250	
Landscaping	$100,000	
Consultant Fees	$1,059,625	
Other	$ 880,890	
Subtotal Miscellaneous Costs		$9,450,345
Total Capital Cost		$19,392,165

In Section IX, page 186, the applicants also project that start up and initial operating expenses will be $2,649,162. In Section VIII.3, page 181, and Section IX, page 186, the applicants state the capital and working capital needs of the project will be financed with unrestricted cash of CHS. Exhibit 31 includes a letter from Carolinas HealthCare System indicating its ability and willingness to allocate reserve funds in the amount of $2,200,000 for purchase of the land for the proposed project:

"...As the Senior Vice President of Corporate Services for Carolinas HealthCare System responsible for real estate services, I am familiar with the organization's financial position. The total capital expenditure for the land acquisition is estimated to be $6,655,000. The allocated cost for the healthplex project is $2,200,000. Please note the entire site was purchased for $250,000 per acre; the allocated portion of land costs assigned to the healthplex project is based on $275,000 to account for related acquisition expenses.

Carolinas HealthCare System will fund this capital cost from existing accumulated cash reserves. This expenditure will not impact any other capital projects currently underway or planned for at this time. For verification of the availability of these funds and our ability to finance these projects internally, please refer to the Line 'Other Assets: Designated as Funded Depreciation,' in the audited financial statements..."

Exhibit 31 also includes a letter from Carol Davis, Chief Financial Officer, Carolinas Medical Center-Union stating the following

"Union Memorial Regional Medical Center, Inc. d/b/a Carolinas Medical Center-Union (CMC-Union) is committed to funding its portion of the

capital needs of the proposed CMC-Union Healthplex, which are approximately $17,192,165. In addition, CMC-Union will fund the start-up and initial operating expenses for the proposed project, which are approximately $2,649,162. As is noted in the 2005 financial statements in the application, Union Memorial Regional Medical Center, Inc. d/b/a CMC-Union has more than sufficient reserves to fund this project and other ongoing projects and will use it (sic) *reserve funds for this project. Specifically, page 8 of these financial statements shown (sic) that Union Memorial Regional Medical Center, Inc. d/b/a CMC-Union has $46,858,000 available as 'CURRENT ASSETS: ASSETS WHOSE USE IS LIMITED.'"*

However, the applicants did not adequately demonstrate that all construction costs were included in the projected total capital costs of the project. Specifically, in Exhibit 25, the architect certifies the probable cost of construction as $7,561,675, as follows:

"The probable cost of construction is based on our healthcare experience and the recent construction experience of Carolinas HealthCare System. Based on this collective information, BBH Design, PLLC based on the best of out (sic) *knowledge and professional experience estimate the probable cost of construction as $7,561,675.00 and should be sufficient to complete this work.*

This estimated (sic, estimate) *does not include soft costs, medical equipment, furniture or furnishings or other related expenses."*

In comparison, the construction contract cost identified by the applicants in Section VIII, page 180 is $6,358,420, or $1,203,255 less than the $7,561,675 cost stated in the architect's letter. On the other hand, if the certified cost includes site preparation costs ($1,383,400), then the total cost of construction would be $7,741,820 or $80,145 more than reported in the architect's letter. However, the applicants did not adequately demonstrate that the site preparation costs are included in the architect's estimate. Consequently, the applicants did not adequately demonstrate that their capital costs are based on reasonable projections or that sufficient funds have been committed for the additional capital costs.

In the projected revenue and expense statement, the applicants project revenues will exceed operating costs at CMC-Union Healthplex in each of the first three operating years. However, the assumptions used by the applicants in projecting utilization are unreasonable, and result in overestimating the number of visits and procedures to be provided. Therefore the projected expenses and revenues which are based on unreasonable utilization projections are unreliable. See the Financials Tab of the application for the pro formas and Section X.10(b), pages 200-202 for the assumptions. See Criterion (3) for discussion of utilization projections.

In summary, the applicants failed to demonstrate the availability of adequate funds for the additional capital costs and failed to demonstrate that the financial feasibility of the project is based upon reasonable projections of costs and revenues. Therefore, the application is nonconforming with this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

CMC-Union Healthplex proposes to develop a freestanding ED with outpatient imaging and diagnostic services in Waxhaw, which will be licensed as part of CMC-Union. The applicants propose to provide the following services: laboratory, pharmacy, observation, X-ray, CT scanner, mobile MRI scanner, and ultrasound. In Section III.7, page 138, the applicants state

"...there are no providers of the proposed services in the four zip code service area; thus, no providers can meet the identified need within the service area."

However, the applicants' service area includes both the primary and secondary service areas from which patients are projected to be served. Further, this service area (primary plus secondary) encompasses more than four zip codes and includes areas in which other providers are located. For this and other reasons, the applicants failed to adequately demonstrate the need for all components of their proposal. See Criterion (3) for discussion. Therefore, the applicants did not adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is nonconforming with this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 172, the applicants provide the projected staffing for CMC-Union Healthplex for the first three operating years. The applicants project to employ a total of 46.5 FTE positions in Year One, 58.0 FTE positions in Year Two and 71.0 FTE positions in Year Three. In Section VII.3, pages 173-174, the applicants state

"As an existing health care provider in the (sic) *Union County and as a part of CHS, CMC-Union has numerous resources from which to obtain staff. CMC, along with Carolinas College of Health Sciences (CCHS),*

provides educational environments for more than 1,000 residents, medical, physician extender, nursing, radiology, and other allied health professional students annually. All of these health professionals use the facilities of CMC-Union to meet their clinical training requirements, and many join the staff of the hospital after their training is completed. In addition, CHS is the fourth largest employer in North and South Carolina, with more than 17,000 clinical, administrative and support personnel on staff. For these reasons, CMC-Union does not expect to have difficulty recruiting the additional FTE's following completion of the proposed project."

The applicants propose 1.0 FTE management position during the first three operating years. In Exhibit 22, the applicants provide letters from current medical directors for CMC-Union who have agreed to continue serving as medical directors for the proposed healthplex. In Section V.3(a), page 153 the applicants state

"The proposed CMC-Union Healthplex will be operated as part of the hospital and will not have its own medical director. The medical directors for each department at the hospital campus will oversee the appropriate department at the proposed healthplex as well. For radiology services, Dr. Robyn Stacy-Humphries is the Medical Director. Dr. Christopher Krubert is the Medical Director for the emergency department and Dr. Kiran Adlakha is the Medical Director for the Laboratory."

The applicants demonstrate the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section IV.5, page 149; Section II.1, pages 38-39; and Section VII.6, pages 174-175, the applicants describe the ancillary and support services that will be provided at CMC-Union Healthplex and the services available from CHS. Exhibit 21 contains copies of existing transfer agreements between CMC-Union and other area healthcare providers. Exhibit 22 contains letters from area physicians supporting the proposal to establish a healthplex in Waxhaw. The applicants adequately demonstrated that the necessary ancillary and support services would be available and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

(iii) would cost no more than if the services were provided by the HMO; and

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NC

Exhibit 3 contains a line drawing of the proposed facility. However, the proposed floor plan in Exhibit 3 identifies only two observation rooms, which is inconsistent with applicants' statement in Section II.1. page 34 that they will *"equip the facility with three observation beds."* Also, the cost of the construction contract in Section VIII, Line 11, on page 180, is about $1.2 million less than the cost identified in the architect's certified cost estimate. See discussion in Criterion 5. Therefore, the applicants did not adequately demonstrate that the cost and design of the proposed construction represent the most reasonable alternative.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.10, page 163, the applicants provide the FY 2005 payor mix for all services provided at CMC-Union, as illustrated in the following table.

FY 2005
CMC-UNION

PAYOR CATEGORY	% OF TOTAL PATIENT DAYS/ PROCEDURES
Medicare	33.8%
Medicaid	42.9%
Managed Care and Commercial Insurance	14.5%
Self Pay/ Indigent/ Charity Care/ Other	8.9%
TOTAL	100.0%

Note: Numbers may not add due to computer rounding

The applicants demonstrated that medically underserved populations currently have adequate access to the services provided at CMC-Union. Therefore, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal

assistance, including the existence of any civil rights access complaints against the applicant;

C

An examination of the licensure and certification files in the Division of Facility Services for CMC-Union, indicates there have been no civil rights access complaints filed against this facility within the last five years.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.2, page 158, the applicants state *"CMC-Union provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay. During FY2005, CMC-Union provided more than $19,500,000, or 8.7 percent of gross revenue, in charity care and bad debt."* In Section VI.12, pages 167-171, the applicants provide the projected payor mix during the second operating year for each service to be provided at CMC-Union Healthplex. The applicants projected that CMC-Union Healthplex's payor mix will be equivalent to the historical payor mix at CMC-Union for the emergency department, CT, MRI, diagnostic X-ray, ultrasound, laboratory and observation beds. See pages 164-167. The applicants demonstrated that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

See Section VI.7, including referenced exhibits, for documentation of the range of means by which patients would have access to the services to be provided at CMC-Union Healthplex. The information provided in the application is reasonable and credible and supports a finding of conformity with this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

See Section V.1, including referenced exhibits, for documentation that CMC-Union Healthplex will accommodate the clinical needs of area health professional training programs. The information provided in the application is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.

(16) Repealed effective July 1, 1987.

(17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

CMC-Union Healthplex did not adequately demonstrate that the proposal would have a positive impact upon the cost effectiveness of the proposed services. See Criteria (3), (5), (6), and (12). Therefore, the application is nonconforming with this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

CMC-Union is accredited by the Joint Commission of Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, DFS, no incidents occurred at the facility, within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC

The applicants propose to acquire an additional CT scanner. However, the application is nonconforming with all applicable *Criteria and Standards for Computed Tomography Equipment* promulgated in 10A NCAC 14C .2300. The specific criteria are discussed below.

The applicants do not propose to acquire any major medical equipment, as defined in N.C. Gen. Stat. §131E-176(14f), other than a CT scanner. Therefore, the *Criteria and Standards for Major Medical Equipment* promulgated in 10A NCAC 14C .3100 are not applicable to this review. Further, CMC-Union Healthplex does not propose to develop any ORs in the proposed facility. Therefore, *the Criteria and Standards for Surgical Services and Operating Rooms* promulgated in 10A NCAC 14C .2100 are not applicable. In addition, CMC-Union Healthplex does not propose to develop any licensed GI endoscopy rooms in the proposed facility. Therefore, the *Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities*, promulgated in 10A NCAC 14C .3900 are not applicable. In addition, the proposed facility does not include any licensed acute care beds of any type. Consequently, there are no other rules applicable to the proposed project.

SECTION .2300 CRITERIA AND STANDARDS FOR COMPUTED TOMOGRAPHY SCANNERS

.2302 INFORMATION REQUIRED OF APPLICANT

.2302(a) This rule states *"An applicant proposing to acquire a CT scanner shall use the acute care facility/medical equipment application form."*

-C- The application was submitted on the acute care facility/medical equipment application form.

.2302(b) This rule states *"An applicant proposing to acquire a CT scanner shall provide the number of CT scans that have been performed on its existing CT scanners for each type of CT scan listed in this Paragraph for the previous 12 month period:*

(1) head scan without contrast;
(2) head scan with contrast;
(3) head scan without and with contrast;
(4) body scan without contrast;
(5) body scan with contrast;
(6) body scan without contrast and with contrast;
(7) biopsy in addition to body scan with or without contrast; and
(8) abscess drainage in addition to body scan with or without contrast."

-C- In Section I.13(a), page 14, the applicants state CHS owns two CT scanners located at CMC-Union. On page 48, the applicants provide the number of CT scans by each type of CT scan performed on the two existing CT scanners at CMC-Union from June 2005-May 2006.

.2302(c) This rule states *"The applicant shall project the number of CT scans to be performed on the new CT scanner for each type of CT scan listed in this Paragraph for the first 12 quarters the new CT scanner is proposed to be operated:*
(1) head scan without contrast;
(2) head scan with contrast;
(3) head scan without and with contrast;
(4) body scan without contrast;
(5) body scan with contrast;
(6) body scan without contrast and with contrast;
(7) biopsy in addition to body scan with or without contrast; and
(8) abscess drainage in addition to body scan with or without contrast."

-C- In Section II.8, pages 48-50, the applicants provide the projected number of scans to be performed on the proposed CT scanner for each type of CT scan listed in this rule for the first 12 quarters of operation of the proposed scanner.

.2302(d) This rule states *"The applicant shall convert the historical and projected number of CT scans to HECT units as follows:*

	Type of CT Scan	No. of Scans		Conversion Factor		HECT Units
1	Head without contrast		X	1.00	=	
2	Head with contrast		X	1.25	=	
3	Head without and with contrast		X	1.75	=	
4	Body without contrast		X	1.50	=	
5	Body with contrast		X	1.75	=	
6	Body without contrast and with contrast		X	2.75	=	
7	Biopsy in addition to body scan with or without contrast		X	2.75 plus body scan HECTs	=	
8	Abscess drainage in addition to body scan with or without contrast		X	4.00 plus body scan HECTs	=	

-C- In Section II.8, page 51, the applicants state *"For all conversions of CT scans to HECT units ..., CMC-Union used the conversion table above."* Also, on page 53, the applicants provided the number of HECT units to be performed on the proposed CT scanner at the CMC-Union Healthplex by its third year of operation.

.2302(e) This rule states *"An applicant proposing to acquire a mobile CT scanner shall provide the information requested in Paragraphs (b), (c), and (d) of this Rule for each proposed host facility."*

-NA- The application does not propose to acquire a mobile CT scanner.

.2302(f) This rule states *"The applicant shall provide all projected direct and indirect operating costs and all projected revenues for the provision of CT services for the first 12 quarters the new CT scanner is proposed to be operated."*

-C- In the pro formas in the Financials tab, the applicants provide the projected direct and indirect operating costs and revenues during the first 12 quarters for the proposed CT scanner.

.2302(g) This rule states *"The applicant shall provide projected costs and projected charges by CPT code for the first 12 quarters the new CT scanner is proposed to be operated."*

-C- In the pro formas in the Financials tab, the applicants provide the projected costs and charges by CPT code during the first 12 quarters for the proposed CT scanner.

.2302(h) This rule states *"If an applicant that has been utilizing a mobile CT scanner proposes to acquire a fixed CT scanner for its facility, the applicant shall demonstrate that its projected charge per CPT code shall not increase more than 10% over its current charge per CPT code on the mobile CT scanner."*

-NA- Neither CMC-Union Healthplex nor CMC-Union has been utilizing a mobile CT scanner.

.2302(i) This rule states *"An applicant proposing to acquire a mobile CT scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities of the new CT scanner."*

-NA- The application does not propose to acquire a mobile CT scanner.

.2302(j) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it has a written commitment from the radiology group of a hospital that it will accept CT readings from the applicant."*

-C- In Exhibit 8, the applicants provide a letter signed by the President of Charlotte Radiology, PA, which states *"We look forward to expanding our relationship with CHS by providing radiology coverage for the CMC-Union Healthplex."* Charlotte Radiology, PA currently provides professional services at all CHS hospitals in the Charlotte region.

.2302(k) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the CT scanner shall be available and staffed for performing CT scan procedures at least 66 hours per week."*

-C- In Section II.8, page 66, the applicants state *"The proposed CT scanner will be staffed and available 66 hours per week for routine, scheduled procedures. This includes 12 hours per day Monday through Friday and six hours on Saturday. In addition, the CT scanner will be available after these hours for emergency procedures."*

.2303 REQUIRED PERFORMANCE STANDARDS

.2303(1) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: (1) each fixed or mobile CT Scanner to be acquired shall be projected*

to perform 5,100 HECT units annually in the third year of operation of the proposed equipment."

-NC- In Section II.8, page 53, the applicants project the proposed CT scanner to be located at CMC-Union Healthplex will perform 7,083 HECT units in the third year of operation following completion of the project. However, as discussed in Criterion (3), projected imaging services volumes (including CT scans) were determined to be unreasonable. Therefore, the projected number of HECT units is likewise unreasonable, and the application is not conforming with this rule. See Criterion (3) for discussion regarding the reasonableness of the projections.

.2303(2) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (2) each existing fixed CT scanner in the applicant's CT service area shall have performed at least 5,100 HECT units in the 12 month period prior to submittal of the application."*

-NC- Pursuant to 10A NCAC 14C .2301(4), *"'Computed tomography (CT) service area' means a geographical area defined by the applicant, which has boundaries that are not farther than 40 road miles from the facility."* In Section II, page 47, the applicants state *"There are no other CT scanners in the CMC-Union Healthplex's CT service area for which data is publicly available."* However, CHS owns Carolinas Imaging Center-Ballantyne at 15110 John J. Delaney Drive, Charlotte, and received a certificate of need in January 2006 to add a fixed CT scanner. The imaging center is located off Highway 521 in Mecklenburg County within the healthplex's proposed secondary service area. See maps on pages 87-88 of the application. The applicants project 20% of the healthplex CT scanner volume to come from the secondary service area, but failed to provide historical utilization for the existing CT scanner they own at Ballantyne Imaging, as required by this rule. Consequently, the applicants are not conforming to this rule.

.2303(3) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (3) each existing and approved fixed CT scanner in the applicant's CT service area shall be projected to perform 5,100 HECT units annually in the third year of operation of the proposed equipment."*

-NC- In Section II.8, page 54, the applicants state *"There are no other CT scanners in CMC-Union Healthplex's CT service area for which data is publicly available."* However, CHS owns Carolinas Imaging Center-Ballantyne at 15110 John J. Delaney Drive, Charlotte, and received a certificate of need in January 2006 to add a fixed CT scanner. The imaging center is located off Highway 521 in Mecklenburg County within the healthplex's proposed secondary service area. See maps on pages 87-88 of the application. The applicants project 20% of the healthplex CT scanner volume to come from the secondary service area, but failed to provide projected utilization for the existing CT scanner they own at Ballantyne Imaging, as required by this rule. Consequently, the applicants are not conforming to this rule.

.2303(4) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (4) each existing mobile CT scanner in the proposed CT service area performed at least an average of 20 HECT units per day per site in the CT scanner service area in the 12 months prior to submittal of the application."*

-NA- In Section II.8, page 54, the applicants state *"CMC-Union is not aware of any mobile CT scanners in the proposed CT service area. If such a scanner exists, it does not appear that it publicly reports its utilization data."*

.2303(5) This rule states *"An applicant proposing to acquire a CT Scanner shall demonstrate each of the following: ... (5) each existing and approved mobile CT scanner shall perform at least an average of 20 HECT units per day per site in the CT scanner service area in the third year of operation of the proposed equipment."*

-NA- In Section II.8, page 54, the applicants state *"CMC-Union is not aware of any mobile CT scanners in the proposed CT service area. If such a scanner exists, it does not appear that it publicly reports its utilization data."*

.2304 **REQUIRED SUPPORT SERVICES**

.2304(a) This rule states *"An applicant proposing to acquire a CT scanner shall document the availability of the following diagnostic services:*

(1) diagnostic radiology services;
(2) therapeutic radiology services;
(3) nuclear medicine services; and

(4) diagnostic ultrasound services."

-C- In Section II.8, page 54, the applicants state that all of the services listed above will be available to CMC-Union Healthplex patients, either at the healthplex or at CMC-Union. See also, Exhibit 9 for a letter signed by the Vice President of Operations CMC-Union, documenting the availability of the above services.

.2304(b) This rule states *"An applicant proposing to acquire a CT scanner shall document the availability of services through written affiliation or referral agreements to treat patients with the following conditions:*

(1) neurological conditions;
(2) thoracic conditions;
(3) cardiac conditions;
(4) abdominal conditions;
(5) medical oncological conditions;
(6) radiological oncological conditions;
(7) gynecological conditions;
(8) neurosurgical conditions; and
(9) genitourinary and urogenital conditions."

-C- Exhibit 9 contains a letter signed by the Vice President of Operation, CMC-Union, which states the proposed healthplex will be able to treat patients with all of the conditions listed above except neurosurgical, thoracic conditions, radiological and medical oncological conditions, and nuclear medicine services. These services will be available at CMC-Union or through the Carolinas HealthCare System.

.2304(c) This rule states *"An applicant proposing to acquire a mobile CT scanner shall provide:*

(1) referral agreements between each host site and at least one other provider of CT services in the proposed CT service area to document the availability of CT services if patients require them when the mobile unit is not in service at that host site; and
(2) documentation that each of the services listed in Paragraphs (a) and (b) of this Rule shall be available at each host facility or shall be available through written affiliation or referral agreements."

-NA- The application does not propose the acquisition of a mobile CT scanner.

.2305 **REQUIRED STAFFING AND STAFF TRAINING**

.2305(a)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements:*

(1) one board certified radiologist who has had:

(A) training in computed tomography as an integral part of his or her residency training program; or

(B) six months of supervised CT experience under the direction of a qualified diagnostic radiologist; or

(C) at least six months of fellowship training, or its equivalent, in CT; or

(D) an appropriate combination of CT experience and fellowship training equivalent to Parts (a)(1) (A), (B), or (C) of this Rule."

-C- In Section II.8, page 56, the applicants state *"All radiologist* (sic) *on staff at CMC-Union Healthplex will be board certified by the American Board of Radiology. At least one board certified radiologist with qualifications listed above will be present during all hours of operation for the proposed CT scanner. Dr. Robyn Stacy-Humphries currently serves as the Medical Director for CMC-Union's radiology department will also oversee radiology, including CT services, at CMC-Union Healthplex. Please see Exhibit 12 for Dr. Stacy-Humphries' curriculum vitae."*

.2305(a)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following staffing requirements: ... (2) at least one radiology technologist registered by the American Society of Radiologic Technologists shall be present during the hours of operation of the CT unit."*

-C- In Section II.8, page 56, the applicants state *"At least one radiology technologist registered by the American Society of Radiology Technologists will be present during the hours of operation of the CT unit."* In Section VII.1, page 172, the applicants state they will employ 10.0 FTE registered technologists in Year One, 12.5 FTE registered technologists in Year Two and 14.5 FTE registered technologists in Year Three.

.2305(a)(3) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that it can meet the following*

staffing requirements: ... (3) a radiation physicist with training in medical physics shall be available for consultation for the calibration and maintenance of the equipment. The radiation physicist may be an employee or an independent contractor."

-C- In Section II.8, page 57, the applicants state *"Please see Exhibit 10 for a the* (sic) *curriculum vitae for Ms. Beth Franklin, a certified diagnostic radiological physicist, who is a CHS employee. Ms. Franklin will be available for consultation for the calibration and maintenance of the equipment for the CMC-Union Healthplex."*

.2305(b) This rule states *"The applicant shall provide documentation that the diagnostic radiologist has completed CT training in head, spine, body and musculoskeletal imaging."*

-NC- In Section II.8, page 57, the applicants state *"Please see Exhibit 11 for the training requirements for the radiologists who are available to provide support for the CT program at CMC-Union Healthplex. All the radiologists are board certified in diagnostic radiology and will have advanced training in various radiological modalities, including CT..."* However, Exhibit 11 did not contain the training requirements for the radiologists that will provide services at CMC-Union Healthplex.

.2305(c)(1) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: (1) certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support."*

-C- In Section II.8, page 72, the applicants state *"All Clinical staff at CMC-Union are required to be certified in CPR and basic cardiac life support (BCLS). This will continue at the proposed CMC-Union Healthplex. Please see Exhibit 13 for information regarding job requirements and certification for CT technologists."*

.2305(c)(2) This rule states *"An applicant proposing to acquire a CT scanner shall demonstrate that the following staff training is provided: ... (2) an organized program of staff education and training which is integral to the services program and ensures improvements in technique and the proper training of new personnel."*

-NC- The applicants did not provide a response to this rule.

.2305(d)	This rule states *"An applicant proposing to acquire a mobile CT scanner shall document that the requirements in Paragraphs (a) and (b) of this Rule shall be met at each host facility."*
-NA-	The applicants do not propose to acquire a mobile CT scanner.

EXHIBIT

8

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE:	March 30, 2011
FINDINGS DATE:	April 6, 2011
PROJECT ANALYST:	Gebrette Miles
ASSISTANT CHIEF:	Martha Frisone

PROJECT I.D. NUMBER: G-8608-10 / Wake Forest Ambulatory Ventures, LLC / Relocate ambulatory surgical facility (ASF) with 3 ORs from Winston-Salem to Clemmons and convert the ASF from single specialty to multispecialty/ Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Wake Forest Ambulatory Ventures, LLC, a wholly-owned subsidiary of Wake Forest University Health Sciences (WFUHS), proposes to relocate an existing ambulatory surgical facility (ASF) with three operating rooms (ORs) from Maplewood Avenue in Winston-Salem to Clemmons, convert the ASF from single specialty (plastic surgery) to multi-specialty, and develop one new procedure room. The applicant does not propose to increase the total number of ORs in Forsyth County. There are no policies or need determinations in the 2010 State Medical Facilities Plan (SMFP) applicable to this review. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

Wake Forest Ambulatory Ventures, LLC, a wholly-owned subsidiary of Wake Forest University Health Sciences (WFUHS), proposes to relocate an existing ambulatory surgical facility (ASF) with three operating rooms (ORs) from 2901 Maplewood Avenue in Winston-Salem to a new facility in Clemmons, convert the ASF from single specialty (plastic surgery) to multi-specialty, and develop one new procedure room. The ASF, formerly known as the Plastic Surgery Center of North Carolina (PSCNC) was acquired by WFUHS in June 2009. The ORs are not currently in use. The proposed multi-specialty ASF, to be known as the Clemmons Medical Park Ambulatory Surgery Center, will include the following specialties:

- Orthopaedics
- General Surgery
- Obstetrics/Gynecology
- Plastic Surgery
- Otolaryngology

Population to be Served

The following table illustrates patient origin for the ambulatory surgical cases performed at PSCNC, as reported in Section III.7, page 57:

PSCNC Current Patient Origin
FFY 2009

County	% of Total Ambulatory Surgical Cases
Forsyth	64%
Davie	8%
Surry	8%
Davidson	5%
Stokes	3%
Guildford	2%
Yadkin	2%
Ashe	1%
Burke	1%
Virginia	1%
Henderson	1%
Iredell	1%
Mecklenburg	1%
Wilkes	1%
South Carolina	1%
Rockingham	1%
Total	**101%**

*Totals do not foot due to rounding.

(Note: WFUHS acquired PSCNC in June 2009. Thus, the current patient origin reflects that of PSCNC prior to WFUHS' acquisition of the facility.)

The following table illustrates projected patient origin for ambulatory surgical cases and procedure cases to be performed at the proposed ASF, as reported in Section III.6, pages 55-56:

Projected Patient Origin
Ambulatory Surgical Cases
Project Years 1 and 2
(FY 2015 and FY 2016)

County	Total Cases		% of Total Ambulatory Surgical Cases	
	FY 2015	FY 2016	FY 2015	FY 2016
Forsyth	1,614	1,718	57%	57%
Davidson	244	259	9%	9%
Stokes	163	174	6%	6%
Surry	143	152	5%	5%
Wilkes	144	154	5%	5%
Davie	124	133	4%	4%
Yadkin	92	98	3%	3%
Catawba	65	69	2%	2%
Iredell	61	65	2%	2%
Alexander	21	22	1%	1%
Alleghany	25	26	1%	1%
Ashe	23	24	1%	1%
Burke	23	25	1%	1%
Caldwell	32	34	1%	1%
Watauga	35	37	1%	1%
Cabarrus	12	12	0%	0%
Total	**2,821**	**3,001**	**100%**	**100%**

Projected Patient Origin
Procedure Room Cases
Project Years 1 and 2
(FY 2015 and FY 2016)

County	Total Cases		% of Total Ambulatory Surgical Cases	
	FY 2015	FY 2016	FY 2015	FY 2016
Forsyth	146	270	54%	54%
Davidson	25	46	9%	9%
Davie	15	28	6%	6%
Stokes	15	28	6%	6%
Surry	15	28	6%	6%
Yadkin	14	26	5%	5%
Wilkes	11	20	4%	4%
Catawba	7	13	3%	3%
Iredell	8	14	3%	3%
Alleghany	2	3	1%	1%
Burke	4	7	1%	1%
Cabarrus	2	4	1%	1%
Caldwell	2	4	1%	1%
Watauga	2	4	1%	1%
Ashe	1	1	0%	0%
Total	270	499	100%	100%

The applicant adequately identified the population proposed to be served.

Demonstration of Need

Proposed Operating Rooms

In Section III.1(b), page 34, the applicant states,

> *"The need for the proposed freestanding ambulatory surgical facility, with three surgical operating rooms and one minor procedure room, relates to multiple factors that are outlined as follows:*
>
> - *The proposed ASC is needed to support the specialties that will be participating in the new Clemmons Medical Park medical office building*
> - *National Healthcare Trends—Market Shift to Outpatient Setting*

- *Trends within ambulatory surgery demonstrate that the utilization of freestanding ambulatory surgery centers will continue to increase dramatically*
- *Healthcare reform will bring large volumes of newly insured patients into the market, and reduce the number of uninsured Americans by as many as 28 million by 2019. A stated goal of the legislation is to encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Ambulatory surgery centers (ASCs) will represent exactly the type of value-based delivery paradigm the government desires healthcare providers to embrace.*
- *Advances in surgical technologies and anesthesia techniques promote increased demand for ambulatory surgery*
- *Demographic data for Wake Forest Ambulatory Ventures LLC's 16-county outpatient service area show that the growth in the population will increase demand for healthcare services, including ambulatory surgery procedures*
- *Physician letters of support demonstrate that the proposed project is necessary to provide additional surgical capacity"*

In Section III.1(b), pages 35-41, the applicant discusses each of these factors separately.

Development of a Clemmons Medical Office Building

On page 35, the applicant states,

> *"The current Plastic Surgery Center of North Carolina (PSCNC) operating rooms are antiquated and do not meet modern operating room standards. The rooms are outdated and too small to accommodate the modern equipment that is necessary to provide exceptional patient care. WFUHS faculty surgeons consider the current condition of the PSCNC operating rooms to be inadequate and are opposed to utilizing the rooms without renovation. Because the building housing the PSCNC operating rooms is owned by a third party, WFUHS has ceased using the PSCNC operating rooms while Clemmons Medical Park ASC is being developed, unless the CON Section approves their use at another location in the interim. Relocation of the PSCNC ambulatory surgery facility to the Clemmons Medical Park location will provide an opportunity to expand and enhance those operating room assets to improve patient safety as well as operating room efficiency and utilization.*
>
> *In addition to the modernization of antiquated operating rooms, the new location of the ambulatory surgery center will enhance patient care through the co-location of complementary services. Clemmons Medical Park, LLC, a separate legal entity, has proposed to develop a Medical Office Building (MOB) on the property directly adjacent to the proposed site of Clemmons Medical Park ASC. This MOB will be a major medical and surgical multispecialty outpost designed to enhance quality through the co-location of multiple offerings of complementary clinical and ancillary services. In fact, of the five services planned to utilize Clemmons Medical Park ASC operating rooms, three will have clinic at the Clemmons MOB – Orthopedic Surgery,*

Obstetrics & Gynecology, and Otolaryngology. The resulting ambulatory surgery outpost with a full complement of clinic [sic] *and ancillary support services will enhance patient convenience and bring a novel healthcare delivery model to the citizens of WFUBMC's 16-county outpatient service area."*

Market Shift to the Outpatient Setting

On page 35, the applicant states,

"Increasingly complex procedures are continuing to transition from the inpatient to the outpatient setting as new technology enters the marketplace each year. Patients and payors prefer the outpatient setting due to convenience and because of the increased savings associated with providing care in a lower cost setting and improved access to services.

Sg2, a nationally recognized healthcare consulting firm, forecasts a substantially greater increase in outpatient volumes compared to inpatient. In fact, Sg2 data indicates a decline of 12% in inpatient use rates and a growth of 17% in outpatient use rates over the next ten years."

Trends in Ambulatory Surgery

On page 36, the applicant states,

"The 2006 National Survey of Ambulatory Surgery is the principal source for national data on the characteristics of visits to hospital-based and freestanding ambulatory surgery centers. The 2006 National Survey of Ambulatory Surgery includes ambulatory surgery performed on an outpatient basis in hospitals and in freestanding ASCs as well as in specialized rooms such as endoscopy suites and cardiac catheterization laboratories. Data from the 2006 Survey provides important information regarding the types of facilities, services rendered and patient characteristics.

The national total of ambulatory surgery visits increased 66.7 percent during the ten year period, growing from 20,838,000 visits in 1996 to 34,728,000 visits in 2006. Visits to freestanding ambulatory surgery centers ("ASCs") increased 348.8 percent.

For the ten year period, the increase in the number of visits to freestanding ACSs far exceeded the growth in visits to hospital-based ambulatory surgery locations. Advances in surgical technology and changes in payment arrangements have supported the growth of freestanding ambulatory surgery centers."

Increased Demand for Healthcare Due to Healthcare Reform

On page 37, the applicant states,

"Coverage expansion will play a significant role in the demand for healthcare services when the full law is implemented in 2013. As of September 2010, insurers must allow parents to keep an adult child up to age 26 on their health plan and those young adults can't be charged more than any other dependent. Beginning in 2014, individuals with income up to 133% of the federal poverty level will qualify for Medicaid. And those individuals with income below 400% of the federal poverty level will qualify for subsidies to purchase health insurance coverage on newly created state insurance exchanges. And, of course, the legislation mandates the purchase of insurance.

ASCs provide a low-cost, convenient alternative to traditional inpatient care. According to Tracy K. Johnson, Vice President of Health Strategies & Solutions, 'healthcare reform will likely accelerate growth in ambulatory services.' Organizations that begin to implement ambulatory strategies with a focus on cost-effective and patient-centered care will enhance their competitive advantage as the market adapts to the effects of healthcare reform. As the movement towards accountable care organizations gains momentum, healthcare organizations with comprehensive, accessible and coordinated ambulatory services will succeed in addressing the needs of the newly insured. The increase in the number of insured patients will require healthcare organizations to adapt to the increased outpatient volumes. Reform will reward those providers that can manage and coordinate services more cost effectively while improving the quality of care. Wake Forest University Baptist Medical Center views this ambulatory surgery center as a means to establishing the proper continuum of care while addressing the increased need of outpatient services expected with the increase [in] *the insured population."*

Advances in Ambulatory Surgery and Regulatory Changes

On page 38, the applicant states,

"Changes in surgical technologies and anesthesia techniques support the continued shift of surgical procedures to the ambulatory setting. Miniaturization of surgical instruments and implants is making it possible to perform an ever-widening variety of surgical procedures on an outpatient basis, thereby avoiding a costly hospital admission. Many procedures that once required an incision are now performed percutaneously.

...

Along with tremendous changes in surgery technology and anesthesia techniques, the reimbursement for ASC procedures has expanded. In recent years the Centers for Medicare and Medicaid Services (CMS) provided updated and expanded lists of ASC-reimbursed procedures. The ASC procedures are limited to those that do not exceed 90 minutes' operating time and a total of 4 hours of recovery / convalescent time.

Anesthesia must be local or regional, or general of not more than 90 minutes. The regulations also exclude procedures that generally result in major blood loss, prolonged invasion of the body cavity or involve major arteries. The ASC procedures included are:

- *Commonly performed on an inpatient basis but may safely be performed in an ASC;*
- *Not of a type that are commonly performed or that may be safely performed in a physician's office;*
- *Limited to procedures requiring a dedicated operating room or surgical suite and generally requiring a post-operative recovery room or short-term (not overnight) convalescent room; and*
- *Not otherwise excluded from Medicare coverage*

With these changes in surgical procedures and reimbursement regulations, thousands of surgical procedures can now be safely and more cost effectively performed in an ambulatory surgical center. ASCs can improve the quality of care received by the patients and delivered by the physicians.

The surgeons and anesthesiologist that are committed to perform ambulatory surgery cases at Clemmons Medical Park ASC have extensive experience in the use of innovative surgical technologies and anesthesia."

Cost Savings for Ambulatory Surgery Centers (ASCs) as Compared to Hospital Outpatient Surgery

On pages 38-39, the applicant states,

"There are huge cost savings related to ambulatory surgery procedures performed in freestanding ASCs as compared to those in hospital outpatient surgery. For all types of surgical procedures, it was estimated that ASCs provided 1.7 billion dollars in Medicare savings in 2008.

CMS has continued to expand the range of services for which ASCs will be paid a facility fee. CMS currently pays ASCs approximately 60% of the outpatient procedure fees paid to hospitals. Medicare currently reimburses the ASC providers less than the hospital provider because ASCs do not have the overhead related to ancillary services, such as Emergency Departments. Also, Medicare co-payment rates are also significantly lower for ASCs as compared to hospital facilities, saving the ASC patient 45 to 60 percent."

Demographic Data

On page 39, the applicant states,

"Given the approximate location of the Clemmons Medical Park ASC to WFUBMC, the WFUBMC 16-county service area was used to project future demand. The following table summarizes growth projections for the WFUBMC outpatient service area as provided by Thomson-Reuters Healthcare.

Population – WFUBMC 16-County Outpatient Service Area					
Age Group	Actual Population 2000	Estimated Population 2010	2000-2010 Average Annual Growth	Projected Population 2015	2010-2015 Average Annual Growth
0-17	324,284	349,433	0.8%	362,909	0.8%
18-44	536,343	536,928	0.0%	534,495	(0.1%)
45-64	323,373	407,936	2.6%	429,700	1.1%
65+	178,293	219,154	2.3%	258,209	3.6%
Total	1,362,293	1,513,451	1.1%	1,585,313	0.9%

Source: Thomson-Reuters Healthcare Market Planner Plus

The service area population has grown at a consistent rate of 1.1% per year in the past decade and is expected to continue growing by 0.9% per year through 2015. Currently, 56% of the population who receive surgery are ages 45 and over. Therefore, this trend was taken into consideration in our analysis based on the expectation that the 45-64 and 65 and older age groups represent the segment of the population that will most likely utilize the ORs proposed in this project. Those age groups were estimated to grow 2.6% per year and 2.3% per year respectively for the period 2000-2010. These two cohorts are expected to experience continued growth at a rate of 1.1% for ages 45-64 and 3.6% for those aged 65 and higher between 2010 and 2015.

Pediatric information is included in order to provide a complete picture of the age distribution; however, all of the ORs in the proposed project are expected to be utilized by patients 17 and older. With a total net gain of 71,862 residents, the population in the service area will have increased demand for healthcare services including ambulatory surgery."

Physician Support

On pages 39, the applicant states,

"The need for the proposed project is consistent with the high demand for ambulatory surgical procedures and the widespread support from numerous surgeons who practice in Forsyth County. These surgeons are members of large General Surgery and Orthopedic physicians groups that have documented their intent to recruit additional surgeons.

In addition to the above surgical cases that are to be performed in the three operating rooms, community physicians have specific recruitment plans. New surgeons will be recruited and encouraged to perform surgical cases at the proposed facility. These newly recruited surgeons are expected to obtain privileges at the facility and at least one hospital in the service area. The applicant expects that these surgeons will perform a total of 3,197 ambulatory surgical cases by project year 3 at the proposed facility."

Proposed Procedure Room

In Section III.1(b), page 41, the applicant discusses the need for the proposed procedure room. The applicant states,

"Over the past several decades, the healthcare system and the advent of new technology and innovation has made frequent changes to how various surgical procedures are performed. Currently, some procedures must be performed in an inpatient OR (such as open heart), while other procedures (such as partial knee replacements) do not need to be performed in an inpatient OR. Further, there are many procedures that could be performed in either an operating room or procedure rooms. The determination about which of those rooms is most appropriate depends on the specific procedure and the circumstantial needs that are specific to an individual patient. The types of individual patient needs is based on medical judgment and include co-morbidities, complications, the patient's age, patient weight, anesthesia needs and other factors.

...

The applicant believes that the benefit of having an adequate supply of procedure rooms is valuable for both the proposed facility and the community."

Projected Utilization—Operating Rooms

In Section IV, page 63, the applicant provides the projected OR utilization at the proposed ASF through the third operating year of the proposed project, as shown in the following table:

Surgical Operating Rooms	Project Year 1 (FY 2015)	Project Year 2 (FY 2016)	Project Year 3 (FY 2017)
# of Dedicated Inpatient ORs	0	0	0
# of Dedicated Outpatient ORs	0	0	0
# of Dedicated Ambulatory ORs	3	3	3
# of Outpatient Surgical Cases	2,821	3,001	3,197

As shown in the table above, the applicant projects to perform 3,197 outpatient surgical cases in three ORs by Project Year 3.

In Section III.1(b), pages 41-47, the applicant provides the methodology and assumptions used to project utilization of the proposed operating rooms. On page 41-42, the applicant states,

> *"The planning process included a review of historical growth rates for surgical case volumes, assessment of current and future capacity constraints and proposed growth methodologies to project future OR demand. Population growth of our 16-county service area and the growth rates reported in recently submitted Certificate of Need applications were considered as well. The projections were vetted through senior leadership and growth rates that reflect all of these variables were developed."*

Step 1

In Step 1, the applicant defines the patient population to be served. On page 42, the applicant states,

> *"In order to project future demand for surgical services, the applicant began by identifying all inpatient and outpatient patient status cases performed at the Inpatient, Outpatient, and Pediatric Surgical Center sites that are on NCBH's license in the date range July 1, 2005 through June 30, 2010 for all surgical specialties. Currently NCBH is licensed for 40 ORs, all of which are located in Ardmore Tower."*

Note: On June 10, 2010, North Carolina Baptist Hospital (NCBH) was approved to construct a new building (to be known as the West Campus Surgery Center) to house eight operating rooms (seven additional and one relocated), two procedure rooms, one robotic surgery training room, and one simulation operating room (Project I.D. #G-8460-10). Thus, upon completion of that project, NCBH will be licensed for 47 ORs. That decision is currently under appeal.

Step 2

On page 42, the applicant determined the historical growth in inpatient and outpatient surgical case volumes at NCBH from FY 2006 to FY 2010, as shown in the following table:

Year				*Cumulative Growth Rate*	*IP Growth Rate*	*OP Growth Rate*
	IP	*OP*	*Total*			
FY 2006	*11,435*	*16,029*	*27,464*	-	-	-
FY 2007	*12,428*	*16,165*	*28,593*	*4.11%*	*8.68%*	*0.85%*
FY 2008	*12,743*	*17,654*	*30,397*	*6.31%*	*2.53%*	*9.21%*
FY 2009	*13,446*	*18,683*	*32,129*	*5.70%*	*5.52%*	*5.83%*
FY 2010	*12,848*	*20,133*	*32,981*	*2.65%*	*-4.45%*	*7.76%*
CAGR (compounded annual growth rate)				*4.7%*	*3.0%*	*5.9%*

On page 42, the applicant states,

> *"WFUBMC has experienced a 4.7% total increase in the number of surgical case volumes between Fiscal Years 2006 and 2010, with a CAGR of a CAGR of 4.7%. Inpatient surgical case volumes had a CAGR of 3.0% and outpatient surgical case volumes, which grew at a rate higher than that of inpatient surgeries, increased, on average, by 5.9% annually.*
>
> *It is important to note, OR case volumes in FY 2006 were negatively impacted by the 2005 Blue Cross and Blue Shield of North Carolina (BCBSNC) Contract Negotiations, which resulted in a contract termination of June 4, 2005 followed by a renewal on October 7, 2005. Despite public offers by NCBH to continue to treat BCBSNC patients on terms equivalent to the previous contract and even though the Wake Forest University Health Sciences (WFUHS) BCBSNC contract remained intact, the patients and referring providers were confused by press coverage of the issue. The NCBH cancellation caused significant disruption in referral patterns resulting in BCBSNC patients seeking care from other BCBSNC providers. Without the BCBSNC disruption, it is likely that the first half of FY 2006 utilization could have been much higher than what was actually experienced during and after that time period. It should be noted that the slow growth between FY 2006 and FY 2007 can also be attributed to significant surgeon turnover."*

As the chart above illustrates, inpatient surgical cases at NCBH increased in each of the last three years. In FY 2010, inpatient surgical cases decreased by 4.45%. However, the applicant provides no explanation as to why this decrease occurred, as was provided for FY 2006 and FY 2007.

Step 3

The applicant used the historical growth rates to estimate future growth rates for inpatient and outpatient surgical cases. On page 43, the applicant states,

> *"Using the historical growth rates along with assumptions for future growth including service area population, trends in ambulatory surgery and the increased demand for healthcare services due to Healthcare Reform, the applicant calculated inpatient and outpatient surgical case volumes for FY 2012 through FY 2014 in the following table utilizing an inpatient growth rate of 4.5% for the interim years and an outpatient growth rate of 6.0% for the same time period.*
>
> *The applicant chose to project future operating room utilization using conservative annual growth rates of 5.0% for inpatient surgeries and 6.25% for outpatient surgeries during the interim years.*

Achievable CAGR		
	IP	*OP*
Interim Years	*4.50%*	*6.00%*
Project Years	*5.00%*	*6.25%*

Interim Years	*IP*	*OP*	*TOTAL*
FY 2012	*14,030*	*22,621*	*36,652*
FY 2013	*14,662*	*23,979*	*38,640*
FY 2014	*15,321*	*25,417*	*40,739*
Project Years			
FY 2015	*16,088*	*27,006*	*43,094*
FY 2016	*16,892*	*28,694*	*45,586*
FY 2017	*17,737*	*30,487*	*48,224"*

The applicant projects inpatient surgical cases will grow at a rate of 4.5% during the interim years and 5.0% during the project years. Based on historical information provided by the applicant on page 42, the CAGR for inpatient surgical cases from FY 2006 to FY 2010 was 3.0%. Information reported on NCBH's license renewal applications (LRAs) from 2006 to 2010 (which uses federal fiscal year data) shows that NCBH performed 11,847 inpatient surgical cases in FFY 2006 and 13,357 inpatient surgical cases in FFY 2010, also resulting in a CAGR of 3.0%. The number of inpatient surgical cases decreased by 4.45% between FY 2009 and FY 2010. However, the applicant provides no explanation as to why this decrease occurred. Furthermore, information reported on NCBH's 2011 LRA (the most recent data available) also shows that inpatient surgical cases declined from FFY 2009 to FFY 2010. In FFY 2009, NCBH performed 13,357 inpatient surgical cases and in FFY 2010, NCBH performed 12,658 inpatient surgical cases, which is a decrease of 5.2% (12,658 – 13,357 = -699 / 13,357 = -5.2%). Thus, the applicant's projected growth rates for inpatient surgical cases of 4.5% during the interim years and 5.0% during the project years are unsupported. Not only are the projected growth rates higher than the CAGR over the past four years, but the number of inpatient surgical cases is decreasing, not increasing. And, unlike the earlier decrease, the applicant provides no explanation to support its assumption that the number of inpatient surgical cases will increase in the future despite the recent decrease.

Step 4

On page 44, the applicant used the projected growth rates in Step 3 and the methodology used to project the need for additional ORs from the 2010 SMFP to determine the number of ORs needed at NCBH through the third year of the proposed project, as shown in the table below:

Year	Inpatient Cases	Inpatient Case Time	Total Inpatient Case Hours	Outpatient Cases	Outpatient Case Time	Total Outpatient Case Hours	Total Combined Hours	Hours per OR per Year	Projected ORs needed in 2017
Interim Years									
FY 2012	14,030	3.0	42,091	22,621	1.5	33,932	76,023	1,872	40.6
FY 2013	14,662	3.0	43,985	23,979	1.5	35,968	79,953	1,872	42.7
FY 2014	15,321	3.0	45,964	25,417	1.5	38,126	84,091	1,872	44.9
Project Years									
FY 2015	16,088	3.0	48,263	27,006	1.5	40,509	88,772	1,872	47.4
FY 2016	16,892	3.0	50,676	28,694	1.5	43,041	93,717	1,872	50.1
FY 2017	17,737	3.0	53,210	30,487	1.5	45,731	98,941	1,872	52.9

As shown in the table above, the applicant states NCBH will need 53 ORs by FY 2017. NCBH is currently licensed for 40 ORs. Thus, the applicant states there will be a deficit of 13 ORs by 2017 (53 – 40 = 13). However, on June 10, 2010, NCBH was approved to develop seven new ORs (Project I.D. #G-8460-10). Upon completion of that project, NCBH would be licensed for 47 ORs. Thus, based on the applicant's assumptions, a deficit of six ORs is projected by 2017 (53 – 47 = 6). On page 44, the applicant states,

> *"Although the above need methodology reveals a system deficit of -12.9 operating rooms, the proposed project does not request approval for incremental ORs. The current project proposes the relocation of 3 existing operating rooms that will allow for a shift of clinically appropriate ambulatory procedures from WFUBMC to the Clemmons Medical Park ASC location."*

However, the applicant's projected need for 53 ORs at NCBH in FY 2017 is overstated because the projected number of inpatient surgical cases is overstated based on unsupported growth rates in the interim and project years. (See Step 3 for discussion.)

Steps 5 and 6

In Step 5, the applicant determined the number of ambulatory surgical cases that would shift from NCBH to the proposed facility in Clemmons. On pages 44-45, the applicant states,

> *"The applicant established criteria to determine what patient population would be appropriate to shift from WFUBMC* [i.e. NCBH]. *First, the applicant identified all outpatient status cases performed at the Inpatient, Outpatient, and Pediatric Surgical Center Sites in the date range July 1, 2009 through June 30, 2010 for all surgical*

specialties. Outpatient status cases were then further filtered to include only adult cases, which was defined as 17 years of age or older at the time of surgery. All pediatric surgical cases will continue to be performed in the pediatric operating rooms at Brenner Children's Hospital.

Further selection refinement was accomplished on this subset of patients by analyzing the types of outpatient surgical procedures that would be appropriate to shift to an off-site location. A comprehensive list of all outpatient surgical procedures that was performed in FY 2010 was created, and OR leadership, with input from a number of surgeons, abbreviated the list to include only low acuity outpatient surgical procedures. The number of cases was determined by reviewing not only the appropriate cases with OR staff, but also takes into consideration the anticipated increases in ambulatory surgical case volumes that will result from the recruitment of additional surgical faculty. Furthermore, the anticipated increases in surgical demand as a result of Healthcare Reform were also considered. Therefore, of the total 20,133, the number of ambulatory surgical cases that fit the aforementioned criteria for FY 2010 was 9,060 cases."

Ratio of Low Acuity/Adult Only Ambulatory Cases Divided into Total Ambulatory Cases	
FY 10 WFUBMC Ambulatory OR Volumes	*20,133*
FY 10 West Campus Volumes	*9,060*
FY 10 Percentage	*45%*

Step 7

On page 45, the applicant applies the percentage of low acuity ambulatory cases calculated in Step 6 (45%) to the projected number of outpatient surgical cases from Step 3 to determine the number of cases to be shifted to the proposed facility in Clemmons, as shown in the table below:

Interim Years	***Projected OP Cases***	***Projected Low Acuity OP Cases to be Shifted***
FY 2012	*22,621*	*10,180*
FY 2013	*23,979*	*10,790*
FY 2014	*25,417*	*11,438*
Project Years		
FY 2015	*27,006*	*12,153*
FY 2016	*28,694*	*12,912*
FY 2017	*30,487*	*13,719*

The applicant states it expects the 45% shift of outpatient cases from NCBH to the proposed facility to remain constant through Project Year 3.

Step 8

On page 46, the applicant applied the methodology used to project the need for additional ORs from the 2010 SMFP to determine the number of ORs needed at NCBH for low acuity outpatient surgical cases through the third year of the proposed project, as shown in the table below:

Interim Years	*Ambulatory Cases*	*Ambulatory Hours*	*Hours/OR*	*ORs*
FY 2012	*10,180*	*15,269*	*1,872*	*8.2*
FY 2013	*10,790*	*16,186*	*1,872*	*8.6*
FY 2014	*11,438*	*17,157*	*1,872*	*9.2*
Project Years				
FY 2015	*12,153*	*18,229*	*1,872*	*9.7*
FY 2016	*12,912*	*19,368*	*1,872*	*10.3*
FY 2017	*13,719*	*20,579*	*1,872*	*11.0*

On page 46, the applicant states,

> *"This analysis resulted in an operating room need of 11.0 ORs by FY 2017 (Project Year 3) to accommodate demand. As specified in this Question (a) (1) (A), for a positive difference of 0.5 or greater, the need is the next highest whole number for fractions of 0.5 or greater. Therefore, a total of 11 operating rooms are needed to accommodate the projected demand for this sub-set of surgical patients."*

Step 9

On page 46, the applicant states,

> *"Based upon the volumes projected in Step 7, the applicant determined the surgical case volumes for select surgical specialties that would shift along with projected incremental growth from the main campus. Those volumes account for 61% of the total Clemmons Medical Park ASC volumes and the remaining 39% will be performed by surgeons from the community. Please see letters from the community surgeons included in Exhibit 12, in which these surgeons state their intention to utilize the new Clemmons Medical Park ASC. The projected Clemmons Medical Park ASC low acuity ambulatory case volumes are presented in the following table.*

Interim Years	*Ambulatory Cases*	*Low Acuity Ambulatory Cases*	*Clemmons Medical Park ASC Low Acuity/Ambulatory Cases*
FY 2012	*22,621*	*10,180*	-
FY 2013	*23,979*	*10,790*	-
FY 2014	*25,417*	*11,438*	-
Project Years			
FY 2015	*27,006*	*12,153*	*2,821*
FY 2016	*28,694*	*12,912*	*3,001*
FY 2017	*30,487*	*13,719*	*3,197*

**The proposed Clemmons Medical Park ASC is projected to be operational in July 2014.*

On page 47, the applicant states,

> *"It is important to note that the projected surgical volumes for this project were adjusted to reflect the projected ambulatory surgical cases and hours represented in* [the] *Davie Certificate of Need (CON ID# G-8078-08), FMC/Clemmons Medical Center Certificate of Need (CON ID# G-8165-08) and NCBH – Policy AC-3 OR Certificate of Need (CON ID# G-8460-10). Furthermore, surgical cases projected in the West Campus CON are inclusive of all surgical specialties (Dentistry, Otolaryngology, General Surgery, General Pediatrics, General Vascular, Gynecology, Neurosurgery, Ophthalmology, Orthopedics, Physiatry, Plastics and Urology), whereas, the surgical specialties slated for the proposed Clemmons ASC reflects only a small subset (Orthopedics, General Surgery, Obstetrics/Gynecology, Otolaryngology and Plastics).* [Emphasis added.]
>
> *As previously discussed, select surgical specialties were indentified to shift to Clemmons Medical Park ASC and the percentage of total ASC volumes by specialty are outlined in the table below.*

Clemmons ASC Surgical Service Mix	*Percent of Total*
Orthopedics	*42%*
General Surgery	*22%*
Obstetrics/Gynecology	*17%*
Otolaryngology	*11%*
Plastics	*8%"*

The applicant says it adjusted volumes to account for three recently approved projects involving ORs in Forsyth and Davie counties. However, the applicant fails to provide any explanation of how it "adjusted" volumes to reflect the development of the replacement Davie County Hospital, the Clemmons campus of Forsyth Medical Center, or the approval of seven additional dedicated outpatient ORs at NCBH. The FMC Clemmons Medical Center

project includes the relocation of five shared ORs from Winston-Salem to Clemmons. Like the proposed ASF in Clemmons, the FMC Clemmons Medical Center will also provide outpatient surgical services and will be located less than three miles from the proposed ASF. The replacement Davie County Hospital project includes the relocation of two shared ORs from Mocksville to Bermuda Run, approximately 9.5 miles from the proposed ASF. The West Campus Surgery Center project includes the development of seven additional dedicated ambulatory ORs and will be located on the campus of NCBH, approximately 8.7 miles from the proposed ASF. Some of the same WFUHS surgeons who will utilize the proposed ASF in Clemmons are expected to utilize the new ORs at NCBH. All three of these facilities will perform outpatient surgical cases in the replacement/new ORs. Given that there is no explanation of how volumes were adjusted, the applicant does not adequately demonstrate that it took these recently approved projects into account when it proposed to relocate the PSCNC ORs to Clemmons and to convert them from single specialty to multi-specialty.

In Section III.1(b), page 40, the applicant provides a table listing the physicians, by specialty, projected to utilize the three ORs at the proposed facility in Clemmons, and the number of cases projected to be performed, by physician, in each of the project years. Letters of support from the physicians listed on page 40 are included in Exhibit 12. The following table summarizes the number of cases, by specialty, projected to be performed:

	# of Surgical Cases		
Specialty	**PY 1**	**PY 2**	**PY 3**
Orthopaedic Surgery	801	1,077	1,376
ENT	159	183	208
General Surgery	331	377	430
OB/GYN	186	213	237
Plastic Surgery	122	140	160
"Additional Recruitment"	1,222	1,011	786
Total	**2,821**	**3,001**	**3,197**

However, prior to the beginning of the review of this project, an orthopaedic physician group consisting of four physicians withdrew its support for the proposed project, including the estimated number of cases projected to be performed by the physician group at the proposed facility. The physician group had projected to perform a total of 180 cases in Project Year 1, 355 cases in Project Year 2, and 545 cases in Project Year 3. Thus, the number of surgical cases projected to be performed is overstated by 180 cases in Project Year 1 (801 – 621 = 180), 355 cases in Project Year 2 (1,077 – 722 = 355), and 545 cases in Project Year 3 (1,376 – 831 = 545). The following table summarizes the number of cases, by specialty, projected to be performed minus the cases that were projected to be performed by the physician group that withdrew its support for the proposed project:

	# of Surgical Cases		
Specialty	**PY 1**	**PY 2**	**PY 3**
Orthopaedic Surgery	*621*	*722*	*831*
ENT	159	183	208
General Surgery	331	377	430
OB/GYN	186	213	237
Plastic Surgery	122	140	160
"Additional Recruitment"	1,222	1,011	786
Total	**2,641**	**2,646**	**2,652**

Additionally, in Section III.1(b), pages 40-41, the applicant states,

> *"In addition to the above surgical cases that are to be performed in the three operating rooms, community physicians have specific recruitment plans. New surgeons will be recruited and encouraged to perform surgical cases at the proposed facility. These newly recruited surgeons are expected to obtain privileges at the facility and at least one hospital in the service area. The applicant expects that these surgeons will perform a total of 3,197 ambulatory surgical cases by project year 3 at the proposed facility. Please see Exhibit 13 for documentation regarding physician recruitment."* [Emphasis added.]

Exhibit 13 includes letters from 5 Wake Forest University Department Chairs which describe WFUHS' planned recruitment of the following:

- 9 additional Orthopaedic Surgery faculty members
- 4 additional Otolaryngology faculty members
- 6 additional General Surgery faculty members
- 3 additional Obstetrics and Gynecology faculty members
- 6 additional Plastic and Reconstructive Surgery faculty members

However, the new physicians listed above are not "community physicians." These will be faculty members of WFUHS.

Exhibit 13 also includes a letter from the Executive Director of WFU Physicians and Vice President of Regional Business Development for WFUBMC, which states,

> *"As the Executive Director of Wake Forest University Physicians and Vice President of Regional Business Development for Wake Forest University Baptist Medical Center, I am actively recruiting physicians from the surrounding communities to utilize the proposed Clemmons Medical Park Ambulatory Surgery Center (ASC). At present, several individual physicians and physician groups have expressed a strong interest in operating at Clemmons Medical Park ASC given that there are currently*

no other multispecialty ASC options available in Forsyth County. I am certain that we will have adequate support for the operating rooms by Project Year 1.

In addition to the physicians that have presently expressed a strong interest in Clemmons Medical Park ASC, I plan to continue physician recruitment efforts during the four year span between Clemmons Medical Park ASC CON approval and Project Year 1. The additional recruitment combined with the current interest in operating at Clemmons Medical Park ASC will result in case volumes necessary to support the three operating rooms." [Emphasis added.]

However, the applicant does not provide any letters of support from any community physicians or physician groups regarding their willingness to utilize the ORs at the proposed facility, the number of surgical cases they expect to perform, or the number of additional physicians they expect to recruit. [The orthopaedic physicians that withdrew their support were the only community physicians (i.e. not faculty members of WFUHS) to provide letters.] Therefore, the applicant does not adequately demonstrate that projected utilization based on its assumptions that "community physicians" will utilize the proposed ASF and recruit additional "community physicians" is reasonable and supported.

Furthermore, the applicant does not discuss the potential impact on existing and approved ORs in Forsyth and Davie counties of shifting patients from other facilities which is likely if "community physicians" are expected to perform 39% of the total number of cases to be performed at the proposed ASF. Additionally, the applicant fails to explain why that number is expected to decline from 1,222 cases in Project Year 1 to only 786 cases in Project Year 3.

In summary, the number of surgical cases projected to be performed in the first three project years based on utilization by "community physicians" is unsupported. As a result, the projected number of surgical cases to be performed in the first three operating years that the applicant attributes to "additional recruitment" (1,222 cases in Project Year 1, 1,011 cases in Project Year 2, and 786 cases in Project Year 3) is also overstated.

Step 10

On page 47, the applicant applied the methodology used in the 2010 SMFP to determine the number of ORs needed at the proposed ASF, as shown in the following table:

	Projected Ambulatory Cases	Ambulatory Case Time	Ambulatory Hours	Hours/ORs	Projected Ambulatory ORs Needed in FY2017
FY2015	2,821	1.5	4,231	1,872	2.3
FY2016	3,001	1.5	4,502	1,872	2.4
FY2017	3,197	1.5	4,796	1,872	2.6

As shown in the table above, the applicant projects a need for 2.6 or, rounding to the next whole number, 3 ORs in Project Year 3. However, after adjusting for the projected number of cases to be performed by the orthopaedic physician group that withdrew its support for the proposed project and the number of cases attributed to "additional recruitment," the applicant demonstrates a need for only two ORs in the third year of proposed project, as illustrated in the table below:

	Projected Ambulatory Cases	Ambulatory Case Time	Ambulatory Hours	Hours/ORs	Projected Ambulatory ORs Needed in FY2017
FY2015	1,419	1.5	2,129	1,872	1.1
FY2016	1,653	1.5	2,480	1,872	1.3
FY2017	1,866	1.5	2,799	1,872	1.5

Thus, the applicant's projected OR need by Project Year 3 is overstated by at least one OR.

Projected Utilization—Procedure Room

The applicant proposes to develop one procedure room at the proposed facility. In Section IV, page 63, the applicant provides the projected utilization of the proposed procedure room through the third operating year of the proposed project, as shown in the following table:

Procedure Room	Project Year 1 (2015)	Project Year 2 (2016)	Project Year 3 (2017)
# of Procedure Rooms	1	1	1
# of Procedure Room Cases	270	499	750

As shown in the table above, the applicant projects to perform 750 procedure room cases in one procedure room by Project Year 3.

In Section III.1(b), pages 48-50, the applicant provides the methodology and assumptions used to project utilization of the proposed procedure room.

Step 1

In this step, the applicant analyzed the growth in the number of procedure room cases performed by WFUHS physicians at NCBH. On page 48, the applicant states,

> *"The applicant reviewed historical data for Fiscal Years 2005 through 2010 in order to determine volume growth and trends occurring specifically to surgical procedures performed in its* [sic, the rooms are part of NCBH, which is not the applicant] *procedure rooms located in CompRehab Plaza. It must be noted that procedures performed in the six Interventional Radiology (IR) rooms and five Cardiac Cath room* [sic] *were excluded as neither the rooms nor the cases would be appropriate in the methodology calculations. Both the IR rooms and the Cardiac Cath rooms require*

very specific equipment and faculty who perform the procedures, and in the case of the six IR rooms, radiologists perform the procedures not the surgeons.

...

An analysis of WFUBMC patient records was further conducted for the last six fiscal years to identify patient cases that would be eligible to be performed in a procedure room. The analysis excluded emergency room patients, all endoscopy patients, all interventional radiology patients, all cardiac cath patients and all patients whose procedure [sic] *were done in an operating room. The data in the table below indicates that, overall, the number of procedures performed at CompRehab has experienced an increase in the number of cases by over 200% in the last six years.*

Fiscal Year	*Cases Performed in a Procedure Room Volume*	*% Change from PY* [Previous Year]
2005	*1,032*	
2006	*1,344*	*30.23%*
2007	*1,992*	*48.21%*
2008	*2,798*	*40.46%*
2009	*3,217*	*14.97%*
2010	*3,458*	*7.49%*

**CompRehab Procedure Room opened in 2005.*

Step 2

The applicant states the hours of operation at CompRehab are 6:45 am – 5:00 pm, Monday through Friday. On page 49, the applicant states,

> *"The capacity of each procedure rooms* [sic] *depends on several factors, such as complexity of the procedure, patient condition and urgency of procedure." However, for purposes of this CON application the capacity for each procedure room is determined to be 4 cases per day for 260 days per year, for a total annual capacity of 1,040 cases per procedure room, and a total annual capacity for the three rooms of 3,120."*

Step 3

On pages 49-50, the applicants discuss the historical growth in the number of procedures at CompRehab. On page 49, the applicant states,

> *"Since 2005, the volume of outpatient procedure cases has grown by over 200%.*
>
> ...

Based on its own 4 year historical growth rate, the applicant chose to utilize a conservative 7.5% growth rate for the three project years. Wake Forest Ambulatory Ventures, LLC believes this a [sic] *growth rate is supportable based on the following assumptions:*

- *Historical growth in cases performed in procedure rooms are expected to continue growing at a slower pace than the preceding five years. The slowdown in growth can be seen in the FY 08, FY 09 and FY 10 change.*
- *WFUHS has recruited additional physicians that will continue to contribute to the increase in procedure case volumes at WFUBMC. These faculty recruits are anticipated to increase the volume of implantable pain devices as well as the number of urologic cases referred for prostate biopsies and other treatment."*

The applicant states that projected procedure room volumes will be split between CompRehab, the West Campus Surgery Center (NCBH was approved to develop two procedure rooms as part of Project I.D. # G-8460-10), and the proposed ASF facility in Clemmons. The applicant's methodology and assumptions results in the need for a total of six procedure rooms in Project Year 3, as illustrated in the following table:

Year	# of Procedures	Procedure Room Capacity	Total # of Procedure Rooms Needed	# of CompRehab Procedures	# of West Campus Surgery Center Procedures	# of Clemmons ASC Procedures	Total Procedure Room Procedures
FY 2008	2,798	1,040	3	2,798	-	-	2,798
FY 2009	3,217	1,040	3	3,217	-	-	3,217
FY 2010	3,458	1,040	3	3,458	-	-	3,426
Interim Years							
FY 2011	3,717	1,040	4	3,717	-	-	3,649
FY 2012	3,996	1,040	4	3,996	-	-	3,886
FY 2013	4,296	1,040	4	2,802	1,494	-	4,139
FY 2014	4,618	1,040	4	3,013	1,605	-	4,408
Project Years							
FY 2015	4,964	1,040	5	3,062	1,632	270	4,694
FY 2016	5,337	1,040	5	3,084	1,754	499	5,337
FY 2017	5,737	1,040	6	3,102	1,885	750	5,737

As shown in the table above, the applicant projects the need for six procedure rooms by Project Year 3. However, the projected number of cases to be performed in the procedure room is not based on reasonable and supported assumptions. One, four orthopaedic surgeons withdrew their support. Two, the applicant's assumptions regarding utilization by other "community physicians" are not adequately documented. See discussion above. Thus, the applicant did not adequately demonstrate the need for the proposed procedure room.

The three PSCNC ORs to be relocated have been chronically underutilized for many years. At present, they are not being utilized. The applicant does not adequately demonstrate the need to construct a replacement facility in Clemmons and to convert PSCNC from a single specialty program to a multi-specialty program for the following reasons:

- Based on historical data for NCBH, the CAGR for inpatient surgical cases from FY 2006 to FY 2010 was 3.0%. However, the number of inpatient surgical cases decreased by 4.45% between FY 2009 to FY 2010. Additionally, LRA data for NCBH shows a decrease of 5.2% from FFY 2009 to FFY 2010. The applicant does not provide an explanation for this decrease or explain why it would be reasonable to assume that inpatient surgical cases will increase in the near future. Thus, the applicant's projected growth rates for inpatient surgical cases of 4.5% and 5.0% during the interim and project years, respectively, are unsupported. Consequently, the applicant's conclusion that NCBH will need 53 ORs by 2017 is also unsupported.

- The applicant does not explain how it "adjusted" volumes to reflect the development of the replacement Davie County Hospital, the Clemmons campus of Forsyth Medical Center, or the approval of seven additional ORs at NCBH. Specifically, the applicant did not provide any data to support its assumptions regarding the potential impact that those existing or approved ORs will have on projected utilization and market shifts in the proposed service area. The approved ORs are all located within 10 miles of the proposed ASF.

- Prior to the beginning of the review of this project, an orthopaedic physician group consisting of four physicians withdrew its support for the proposed project, including the estimated number of cases projected to be performed by the physician group at the proposed facility. The physician group had projected to perform a total of 180 cases in Project Year 1, 355 cases in Project Year 2, and 545 cases in Project Year 3. Thus, the number of outpatient surgical cases projected to be performed is overstated by 180 cases in Project Year 1, 355 cases in Project Year 2, and 545 cases in Project Year 3.

  The applicant assumes 39% of all cases will be performed by "community physicians." Presumably, by this, the applicant means these physicians are not faculty members of WFUHS and do not currently perform surgery at NCBH. Instead, they perform surgery at Forsyth Medical Center, Davie County Hospital, Medical Park Hospital, and other community hospitals. The applicant does not adequately demonstrate that any "community physicians" will utilize the proposed ASF. As discussed above, four orthopaedic surgeons withdrew their support for the proposal and indicated they will not be performing surgery in the facility after all. When the cases they were expected to perform are subtracted, the applicant only demonstrates a need for two ORs, not three. Furthermore, the applicant does not address the impact on other facilities, particularly the replacement Davie County Hospital and the Clemmons campus of Forsyth Medical Center, if existing "community physicians" were to shift their surgical cases to the proposed ASF.

The applicant states physicians will be recruited *"from the surrounding communities to utilize the proposed Clemmons Medical Park Ambulatory Surgery Center."* However, the applicant does not provide any letters of support from any "community physicians" or physician groups regarding their willingness to utilize the ORs at the proposed facility, the number of surgical cases they expect to perform, or the number of additional physicians they expect to recruit. In addition, when the cases projected to be performed as a result of "additional recruitment" are subtracted, the applicant only demonstrates a need for two ORs, not three.

Therefore, the applicant does not adequately demonstrate the need for the proposed multispecialty ASF with three ORs in Clemmons.

In summary, the applicant adequately identified the population to be served but did not adequately demonstrate the need that the population has for proposal. Therefore, the application is nonconforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate the three ORs formerly known as PSCNC from Winston-Salem to Clemmons. The applicant acquired PSCNC in June 2009. In FFY 2009, only 148 surgical procedures were performed at PSCNC. Currently, the three ORs at PSCNC are not in use. In Section III.1(b), page 35, the applicant states,

> *"The current Plastic Surgery Center of North Carolina (PSCNC) operating rooms are antiquated and do not meet modern operating room standards. The rooms are outdated and too small to accommodate the modern equipment that is necessary to provide exceptional patient care. WFUHS faculty surgeons consider the current condition of the PSCNC operating rooms to be inadequate and are opposed to utilizing the rooms without renovation. Because the building housing the PSCNC operating rooms is owned by a third party, WFUHS has ceased using the PSCNC operation rooms while Clemmons Medical park ASC is being developed, unless the CON Section approves their use at another location in the interim. Relocation of the PSCNC ambulatory surgery facility to the Clemmons Medical Park location will provide an opportunity to expand and enhance those operating room assets to improve patient safety as well as operating room efficiency and utilization."*

Because the ORs to be relocated are currently not being utilized, no patients will be impacted as a result of the proposed project. The three ORs at PSCNC are located approximately 7.5

miles away from the proposed ASF in Clemmons. Thus, the replacement facility would be geographically accessible to the same population formerly served at the PSCNC. The relocation and replacement of the ORs would have a positive effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care. Consequently, the application is conforming to this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section III.8, pages 57-58, the applicant describes the alternatives considered:

- Maintain the status quo
- Relocate the ORs to the NCBH campus
- Develop a freestanding ambulatory surgical center in Winston-Salem
- Develop a freestanding ambulatory surgical center in Clemmons

However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (18a), and the Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100. Therefore, the applicant did not adequately demonstrate that the proposal is its least costly or most effective alternative and the application is nonconforming to this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

NC

In Section VIII, pages 83-84, the applicant projects the total capital expenditure for the project will be $8,553,928, which includes $1,024,925 for land purchase and site preparation costs; $3,242,500 for construction costs; $3,468,684 for movable equipment; $60,000 for furniture; $365,700 for consulting fees and engineering fees; and $392,119 for other miscellaneous costs. In Section IX, page 87, the applicant projects start-up expenses of $158,198 and initial operating expenses of $374,270, for a total working capital of $532,468.

The applicant proposes to finance the capital and working capital costs with the accumulated reserves of WFUHS. Wake Forest Ambulatory Ventures LLC is a wholly owned subsidiary of WFUHS. Exhibit 21 contains a letter from the Executive Vice President for Finance and Chief Financial Officer of WFUHS, which states,

"Wake Forest University Health Sciences agrees to make available from its accumulated reserves a total of $8,553,928 for the capital costs incurred in the development of the aforementioned project.

As Treasurer for Wake Forest University Health Sciences, I can attest to the availability of funds for this purpose. These funds will be made available from the accumulated reserves of Wake Forest University Health Sciences. Please reference our audited financial statements, particularly our balance sheet, for evidence that funds are available for this purpose."

Exhibit 21 contains a second letter from the Executive Vice President for Finance and Chief Financial Officer of WFUHS, which states,

"Consistent with the information in the CON application, a total of $532,468 has been identified to provide the working capital necessary to fund the operating expenses expected during the initial operating period. In the event that the initial capital requirements are exceeded by unforeseen circumstances such as those defined in NCGS 131E-176(16e), WFUHS will provide the funds necessary to ensure development of the proposed project."

Exhibit 22 contains the audited financial statements for WFUHS. As of June 30, 2010, WFUHS had $9,877,000 in cash and cash equivalents, $1,102,285,000 in total assets, and $559,199,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital and working capital needs of the project.

In the pro forma revenue and expense statements, the applicant projects that revenues will exceed operating costs for the entire facility in each of the first three full operating years of the proposed project. The assumptions used by the applicant are in Section XIII (financial statements). However, the applicant's projected utilization is unsupported and unreliable. Thus, costs and revenues that are based on this projected utilization are also not reliable. See Criterion (3) for discussion of projected utilization. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is nonconforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities for the following reasons: First, the applicant's projected growth rates for inpatient surgical cases are unsupported and unreliable. Thus, the applicant overstates the need for ORs at NCBH. Second, the applicant's assumptions regarding the number of orthopaedic physicians projected to utilize the proposed facility are unsupported and unreliable. Third, the applicant relies on unsupported and unreliable assumptions regarding the number of "community physicians" expected to utilize the proposed ASF. Thus, the number of surgical cases and procedures projected to be performed at the proposed ASF is overstated. Consequently, the number of ORs and procedure rooms needed is overstated. Fourth, the applicant states it made adjustments for the replacement Davie County Hospital, the seven additional ambulatory surgical ORs to be developed at NCBH and the Clemmons campus of Forsyth Medical Center. However, the applicant fails to explain or document how it took these existing and approved ORs into account. See Criterion (3) for additional discussion. Therefore, the application is nonconforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 74, the applicant provides the projected staffing for the proposed facility. The applicant projects that the proposed facility will be staffed with 24.10 full-time equivalent (FTE) positions in the second year of the project. In Section VII.3(a), page 74, the applicant states that all of these positions are new positions. In Section VII.3(b), pages 74-75, the applicant describes the methods it will use to recruit staff for the new positions. In Section V.3, page 65, the applicant identifies Andrea Fernandez, M.D., as having expressed interest in serving as the medical director for the proposed facility. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and is conforming with this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section II.1, page 10, the applicant provides a list of the necessary ancillary and support services which will be available at the proposed facility. Additionally, in Section II.2(a), page 11, the applicant states that the following professional, ancillary, and support services will be provided by Wake Forest University Baptist Medical Center (WFUBMC):

1. Anesthesiology and CRNA Services
2. Pathology Professional Services
3. Laboratory Services
4. Pharmacy Consulting

In Section V.2(a), page 64, the applicant states it is willing to establish a transfer agreement with WFUBMC. Exhibit 4 contains a copy of a draft transfer agreement between the applicant and WFUBMC. Exhibit 12 includes copies of letters from WFUHS physicians supporting the proposed ASF.

The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv)would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to construct a new 12,500 square foot building for the proposed facility. In Section XI.6(a), the applicant provides details of the square footage allocation, as shown in the table below:

	Total Square Footage / New Construction
Pre/Post-Operative	2,040
Operating and Procedure Rooms	1,890
Administration	460
Support	8,110
Total	**12,500**

The certified estimate of construction costs from the architect, included in Exhibit 10, is consistent with the construction costs reported by the applicant in Section VIII, page 83. In Section XI.6(b), page 124, the applicant estimates construction costs of $684 per square foot. In Section XI.8, page 94, the applicant describes the methods to be used to maintain efficient energy operations.

The applicant adequately demonstrated that the cost, design, and means of construction represent the most reasonable alternative for the project as proposed and that the construction project will not unduly increase the costs and charges of providing health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

In Section VI.12, page 71, the applicant provides the payor mix for PSCNC, as illustrated in the following table.

PSCNC – Current Payor Mix	
Self Pay/Indigent/Charity	100.0%
Commercial	
Medicare/Medicare Managed Care	
Medicaid	
Managed Care	
Other	
TOTAL	**100.0%**

However, the applicant does not indicate the time period for the table above. The Project Analyst concluded that the payor mix shown in the table above reflects the payor mix of the plastic surgery practice prior to WFUHS' acquisition of the ORs at PSCNC. In Section II.10, page 19, the applicant provides a list of the 20 procedures performed at PSCNC in the 12 months preceding submittal of the application. It appears many of the procedures performed at PSCNC would not have been reimbursed by Medicare or Medicaid, thereby limiting the extent to which medically underserved populations had access to services at the facility. Furthermore, in Section III.(b), page 35, the applicant states that the three ORs at the PSCNC are currently not in use. The applicant states, *"Because the building housing the PSCNC operating rooms is owned by a third party, WFUHS has ceased using the PSCNC operating rooms while Clemmons Medical Park ASC is being developed..."* Therefore, this criterion is not applicable to this application.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.10(a), page 70, the applicant states, *"Clemmons Medical Park ASC is a new entitiy and has no civil rights equal access complaints on file. No civil rights equal access complaints have been filed against WFUHS or any facilities or services owned by WFUHS in North Carolina in the last five years."* The application is conforming with this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14, pages 71-72, the applicant projects the following payor mix for the proposed facility in Project Year 2, as illustrated in the following tables.

FY 2016 Clemmons Medical Park ORs	
Self Pay/Indigent/Charity	6.11%
Commercial Insurance/Managed Care	50.38%
Medicare/Medicare Managed Care	35.75%
Medicaid	7.76%
TOTAL	**100.00%**

FY 2016 Clemmons Medical Park Procedure Room	
Self Pay/Indigent/Charity	4.41%%
Commercial Insurance/Managed Care	35.47%
Medicare/Medicare Managed Care	12.63%
Medicaid	47.49%
TOTAL	**100.00%**

In Section VI.14, page 72, the applicant states that the projected payor mix for the proposed services are based on WFUBMC's historical experience. The applicant demonstrates that medically underserved groups would have adequate access to the proposed services, and the application is conforming with this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 70, the applicant states,

> *"Physicians with privileges at the facility may refer and schedule patients for procedures. Clemmons Medical Park ASC physicians are expected to receive patient referrals from a large base of primary care physicians in the region."*

The applicant adequately demonstrated that would offer a range of means by which patients would have access to the proposed services. The application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

NC

In Section V.1(a), page 64, the applicant states,

"As an academic medical center that has been providing services for more than 85 years, WFUBMC [this is not the applicant] *has established relationships with many clinical training programs in the southeast and continues to provide teaching opportunities for these schools. The clinical staff at Clemmons Medical Park ASC will be provided the same access to the existing clinical training programs at WFUBMC. As an academic medical center with recognized national and international expertise in surgery, WFUBMC is one of only a few hospitals in the state that could promulgate its expertise to a freestanding ambulatory surgery center. Please see Exhibit 15 for a list of educational programs that use WFUBMC's facilities for clinical training."*

The applicant states the staff of the proposed ASF will have access to WFUBMC clinical training programs. However, this criterion requires the applicant to demonstrate that the proposed ASF will serve as a clinical training site as applicable. In Section V.1(b), page 64, the applicant states it *"has offered to serve as a clinical training site for health professional students."* However, the applicant does not provide documentation, such as a letter addressed to an area health professional training program offering the proposed ASF as a clinical training site. Therefore, the applicant does not adequately demonstrate that the proposed ASF would accommodate the clinical needs of area health professional training programs. Thus, the application is nonconforming with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant did not adequately demonstrate that the proposal would have a positive impact on cost-effectiveness, quality and access for the following reasons:

1) the applicant did not adequately demonstrate that the proposal is cost-effective [see Criteria (3) and (5) for additional discussion];
2) the applicant did not adequately demonstrate that the proposal will not result in unnecessary duplication of existing or approved health service capabilities or facilities [see Criteria (3) and (6) for additional discussion]; and

3) the applicant did not adequately document the expected effects of the proposed services on competition in the proposed service area [see Criteria (3) and (6) for additional discussion].

Therefore, the application is nonconforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

NA

Although PSCNC is an existing ASF, WFUHS acquired it in June 2009. At present, the facility is not in use. See Section III.1(b), page 35.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt Rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such Rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NC

The Criteria and Standards for Surgical Services and Operating Rooms, promulgated in 10A NCAC 14C .2100, are applicable to this review. However, the application is not conforming to all applicable Criteria and Standards for Surgical Services and Operating Rooms. The specific criteria are discussed below.

SECTION .2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

.2102 INFORMATION REQUIRED OF APPLICANT

.2102(a) *An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:*

(1) gynecology;
(2) otolaryngology;
(3) plastic surgery;
(4) general surgery;
(5) ophthalmology;
(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

-C- The applicant proposes to convert a single specialty ambulatory surgical program to a multi-specialty ambulatory surgical program. In Section II.10, page 16, the applicant states the following specialty areas will be provided in the facility:

- Orthopedics
- Obstetrics/Gynecology
- Otolaryngology
- Plastics
- General Surgery

.2102(b) An applicant proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide the following information:

(1) the number and type of operating rooms in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- In Section II.10, page 17, the applicant provides information regarding the number of ORs in each licensed facility owned by WFUMBC. NCBH and WFUHS, separate legal entities, do business as WFUBMC pursuant to an integration agreement. However, the ORs at PSCNC are the only ORs owned by WFUHS in Forsyth County and NCBH does not own a controlling interest in PSCNC. The following table illustrates the number and type of ORs in which WFUHS owns a controlling interest in Forsyth County:

WFUHS Owned Facilities
Current Operating Room Inventory

Type	PSCNC
Dedicated Open Heart	
Other Dedicated Inpatient	
Shared Inpatient/Outpatient	
Dedicated Outpatient	3
Dedicated C-Section	
Total	3

(2) the number and type of operating rooms to be located in each licensed facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- In Section II.10, page 17, the applicant provides information regarding the number of operating rooms to be located in each licensed facility owned by NCBH or WFUHS. However, the ORs at PSCNC are the only ORs owned by WFUHS in Forsyth County and NCBH does not own a controlling interest in PSCNC. The following table illustrates the number and type of ORs to be located in the proposed ASF upon completion of the proposed project in which WFUHS owns a controlling interest in Forsyth County:

WFUHS Owned Facilities
Projected Operating Room Inventory

Type	Clemmons Medical Park ASF
Dedicated Open Heart	
Other Dedicated Inpatient	
Shared Inpatient/Outpatient	
Dedicated Outpatient	3
Dedicated C-Section	
Total	3

(3) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in

the operating rooms in each licensed facility listed in response to Subparagraphs (b)(1) and(b)(2) of this Rule:

-C- In Section II.10, page 18, the applicant provides information regarding the number of inpatient surgical cases (excludes trauma cases, burn center cases, and cases performed in dedicated open heart and dedicated C-Section rooms) and the number of outpatient surgical cases performed in the most recent 12 month period in the ORs in each licensed facility owned by NCBH or WFUHS. However, the ORs at PSCNC are the only ORs owned by WFUHS in Forsyth County and NCBH does not own a controlling interest in PSCNC. The following table illustrates the number surgical cases performed in the most recent 12 month period at PSCNC:

WFUHS Owned Facilities
Total Surgical Cases
July 2009 – June 2010

Type	PSCNC
Inpatient	
Outpatient	165
Total	165

(4) The number of inpatient surgical cases, excluding trauma cases reported by Level I, II and III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-Section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each licensed facility listed in response to Subparagraphs (b)(1) and (b)(2) of this Rule;

-C- In Section II.10, page 18, the applicant provides information regarding the number of inpatient surgical cases (excludes trauma cases, burn center cases, and cases performed in dedicated open heart and dedicated C-Section rooms) and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project in the operating rooms in each licensed facility owned by NCBH or WFUHS. However, the ORs at PSCNC are the only ORs owned by WFUHS in Forsyth County and NCBH does not own a controlling interest in PSCNC. The following table illustrates the number of inpatient and outpatient surgical cases to be performed in each of the first three operating years at the proposed ASF:

WFUHS Owned Facilities
Total Projected Inpatient Surgical Cases
FY 2015 – FY 2017

Type	Clemmons Medical Park ASF
Project Year 1 (FY 2015)	n/a
Project Year 2 (FY 2016)	n/a
Project Year 3 (FY 2017)	n/a

WFUHS Owned Facilities
Total Projected Outpatient Surgical Cases
FY 2015 – FY 2017

Type	Clemmons Medical Park ASF
Project Year 1 (FY 2015)	2,821
Project Year 2 (FY 2016)	3,001
Project Year 3 (FY 2017)	3,197

However, see Criterion (3) for discussion regarding the reasonableness of projected utilization.

(5) A detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

-NC- In Section III.1(b), pages 34-50, the applicant provides a detailed description of the assumptions and methodology used in the development of the projections required by this Rule. However, the assumptions and methodology used to project the number outpatient surgical cases to be performed at the proposed ASF in Clemmons are unreasonable and unsupported. See Criterion (3) for discussion. Therefore, the application is nonconforming to this Rule.

(6) The hours of operation of the proposed operating rooms;

-C- In Section II.10, page 19, the applicant states the hours of operation of the proposed ASF will be 7:00 am to 5:00 pm, Monday through Friday.

(7) If the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;

-C- In Section II.10, page 19, the applicant provides the average reimbursement per procedure for the 20 surgical procedures most commonly performed at

PSCNC during the preceding 12 months. WFUHS received an exemption from the Certificate of Need Section to acquire PSCNC in June 2009. The applicant is a wholly-owned subsidiary of WFUHS.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items in the reimbursement; and

-C- In Section II.10, page 20, the applicant provides the projected average reimbursement per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the proposed ASF.

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- In Section II.10, page 20, the applicant identifies the providers of pre-operative services and procedures which will not be included in the ASF's charge. They are: Anesthesia/CRNA (WFUBMC Anesthesia Department), Pathology (WFUBMC Pathology), and Pharmacy Consulting (WFUBMC Pharmacist).

.2102(c) An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:

(1) the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- PSCNC is currently licensed for three ORs. Upon project completion, the name of the facility and its location within the service area (Forsyth County) will change but the existing ASF would continue to be licensed for three ORs.

(2) the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

-C- PSCNC is currently licensed for three ORs. Upon project completion, the name of the facility and its location within the service area (Forsyth County) will change but the existing ASF would continue to be licensed for three ORs.

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-

section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- In Section II.10, page 22, the applicant provides the number of inpatient surgical cases and outpatient surgical cases performed in the most recent 12 month period in the operating rooms in each facility listed in Subparagraphs (c)(1) and (c)(2) of this Rule:

Type	PSCNC
Inpatient	n/a
Outpatient	165
Total	**165**

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule;

-C- In Section II.10, page 22, the applicant provides the number of inpatient surgical cases and outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c)(1) and (c)(2) of this Rule:

Projected Inpatient Surgical Cases
FY 2015 – FY 2017

Type	Clemmons Medical Park ASC
Project Year 1 (FY 2015)	-
Project Year 2 (FY 2016)	-
Project Year 3 (FY 2017)	-

Projected Outpatient Surgical Cases
FY 2015 – FY 2017

Type	Clemmons Medical Park ASC
Project Year 1 (FY 2015)	2,821
Project Year 2 (FY 2016)	3,001
Project Year 3 (FY 2017)	3,197

However, see Criterion (3) for discussion regarding the reasonableness of projected utilization.

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

-NC- In Section III.1(b), pages 34-50, the applicant provides a detailed description of the assumptions and methodology used in the development of the projections required by this Rule. However, the assumptions used to project the number of outpatient surgical cases at the proposed ASF in Clemmons are unreasonable and unsupported. See Criterion (3) for discussion. Therefore, the application is nonconforming to this Rule.

(6) the hours of operation of the facility to be expanded;

-C- In Section II.10, page 23, the applicant states that the proposed ASF's hours of operation will be 7:00 am to 5:00 pm, Monday through Friday.

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

-C- In Section II.10, page 23, the applicant provides the average reimbursement per procedure for the 20 surgical procedures most commonly performed at PSCNC during the preceding 12 months. WFUHS received an exemption from the Certificate of Need Section to acquire PSCNC in June 2009. The applicant is a wholly-owned subsidiary of WFUHS. The ORs are not currently in use. Thus, it is assumed that the 20 procedures most commonly performed were those performed before WFUHS acquired the facility.

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

-C- In Section II.10, page 24, the applicant provides the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the relocated facility.

9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-C- In Section II.10, page 20, the applicant identifies the providers of pre-operative services and procedures which will not be included in the ASF's charge. They are: Anesthesia/CRNA (WFUBMC Anesthesia Department), Pathology (WFUBMC Pathology), and Pharmacy Consulting (WFUBMC Pharmacist).

.2102(d) *An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:*

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;

(3) a commitment that the Medicare allowable amount for self pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self pay surgical cases;

(7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;

(8) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;

(9) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;

(10) for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;

(11) a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;

(12) a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;

(13) descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;

(14) if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;

(15) a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;

(16) a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;

(17) a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:

(A) patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;

(B) patient outcome results for each of the applicant's patient outcome measures;

(C) the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and

(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the

single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.

-NA- The applicant does not propose to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan.

.2103 PERFORMANCE STANDARDS

.2103(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks per year.

-C- In Section II.10, page 23, the applicant states that the proposed ASF's hours of operation will be 7:00 am to 5:00 pm, Monday through Friday.

.2103(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility, which is proposed to be developed or expanded, in the third operating year of the project is based on the following formula: {[(Number of facility projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-Section rooms, times 3.0 hours) plus (Number of facilities projected outpatient cases times 1.5 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1,872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and the difference is a negative number or a positive number less than 0.2, the need is zero; or

-NC- The service area (Forsyth County) has more than 10 ORs. In Section II.10, page 26, the applicant states it needs three ORs at the proposed facility, as shown in the table below.

	Projected Ambulatory Cases	Ambulatory Case Time	Ambulatory Hours	Hours/ORs	Projected Ambulatory ORs Needed in FY2017
FY2015	2,821	1.5	4,231	1,872	2.3
FY2016	3,001	1.5	4,502	1,872	2.4
FY2017	3,197	1.5	4,796	1,872	2.6

However, projected utilization is not based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the applicant does not adequately demonstrate the need for three ORs and the application is nonconforming to this Rule.

.2103(c) *A proposal to increase the number of operating rooms (excluding dedicated C-Sections operating rooms) in a service area shall:*

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases report by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' times 1.5 hours)] divided by 1,872 hours} minus the total number of existing and approved operating rooms and

operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions of less than 0.2; and if the difference is a negative number or a positive number less than 0.2, the need is zero.

-NA- The applicant does not propose to increase the number of operating rooms in the service area.

.2103(d) *An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.*

-NA- The applicant does not propose to develop an additional dedicated C-section room.

Exhibit D

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: August 26, 2011
FINDINGS DATE: September 2, 2011

PROJECT ANALYST: Gebrette Miles
ASSISTANT CHIEF: Martha Frisone

PROJECT I.D. NUMBER: B-8638-11 / Mission Hospital, Inc / Relocate one gastrointestinal (GI) endoscopy room from the hospital's main campus in Asheville to Fletcher / Buncombe County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Mission Hospital, Inc. proposes to relocate one existing gastrointestinal (GI) endoscopy room from the hospital's main campus in Asheville to Fletcher (Buncombe County). The relocated GI endoscopy room will be licensed as part of the hospital. The applicant does not propose to increase the number of GI endoscopy rooms, increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2011 State Medical Facilities Plan (SMFP). Consequently, there is no need determination in the 2011 SMFP applicable to the proposed project. Furthermore, there are no policies in the 2011 SMFP which are applicable to the proposal. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to

which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

Mission Hospital, Inc. currently operates six licensed gastrointestinal (GI) endoscopy rooms on its main campus, located at 509 Biltmore Avenue in Asheville (Buncombe County). The applicant proposes to relocate one of the existing GI endoscopy rooms from the main campus in Asheville to a medical office building in Fletcher. The relocated GI endoscopy room, to be known as *Mission GI South*, will be licensed as part of the hospital. Consequently, the applicant does not propose to develop a new health service facility. Specifically, a new ambulatory surgical facility.

Population to Be Served

In Section III.5, page 69, the applicant states,

> *"Mission Hospital has a 13-county service area for GI endoscopy services consisting of Buncombe, Henderson, McDowell, Haywood, Madison, Yancey, Transylvania, Mitchell, Jackson, Macon, Cherokee, Burke, and Swain Counties. Mission's GI Endoscopy Service Area also includes 'Other In-Migration,' which are counties and states listed on page 37 of Mission's 2011 LRA included in Exhibit 8."*

In Sections III.6 and III.7, pages 70 and 71, the applicant provides the current and projected patient origin for Mission Hospital GI endoscopy services (inpatient and outpatient). Because the GI endoscopy room proposed to be relocated will remain on the hospital's license, the applicant will continue to operate six GI endoscopy rooms upon completion of the proposed project. The projected patient origin for Mission Hospital, shown in the following table, is inclusive of the proposed Mission GI South location:

Mission Hospital
GI Endoscopy Services
(Inpatient and Outpatient)
Current and Projected Patient Origin

County	Current FY 2010	Project Year 2 CY 2014
Buncombe	56.8%	56.8%
Henderson	6.9%	6.9%
McDowell	5.2%	5.2%
Haywood	5.0%	5.0%
Madison	4.6%	4.6%
Yancey	3.4%	3.4%
Transylvania	2.4%	2.4%
Mitchell	2.2%	2.2%
Jackson	2.1%	2.1%
Macon	1.9%	1.9%
Cherokee	1.6%	1.6%
Burke	1.4%	1.4%
Swain	1.0%	1.0%
In-migration	5.5%	5.5%
Total	100.0%	100.0%

As shown in the table above, nearly 64% of Mission Hospital's current and projected endoscopy patients originate from Buncombe (56.8%) and Henderson (6.9%) counties. Also shown above, the applicant projects that 5.5% of its project patient origin will be the result of in-migration. As previously stated, the projected patient origin shown in the time table above for Mission Hospital includes both the Asheville campus and the proposed Mission GI South campus.

In Section III.1(a), page 30, the applicant states,

> *"Mission analyzed historical utilization of services at Mission from southern Buncombe County and Henderson County, as well as projected population growth in the region to determine the Mission GI South Zip Code Service Area."*

In Section III.1(a), page 37, the applicant identifies the following nine-zip code service area for Mission GI South. [Note: The current and projected patient origin of Mission Hospital's GI endoscopy patients, as shown in the table above, is inclusive of the following nine zip codes. The existing Mission Hospital patients who live in these nine zip codes are currently traveling north to Mission Hospital for GI endoscopy services.]

**Mission GI South
Service Area
by Zip Code**

Zip Code	County
28704	Buncombe
28803	Buncombe
28806	Buncombe
28732	Henderson
28742	Henderson
28758*	Henderson
28759	Henderson
28791	Henderson
28792	Henderson

*This zip code is a P.O. Box.

In Section III.1(a), page 58 and Exhibit 16, Table 5, the applicant provides the projected patient origin for the Mission GI South campus, as illustrated in the table below.

**Mission GI South
Projected Patient Origin**

	PY 1 (CY 2013)		PY 2 (CY 2014)		PY 3 (CY 2015)	
County	# of Procedures	% of Total	# of Procedures	% of Total	# of Procedures	% of Total
Buncombe	1,071	73.6%	1,082	73.6%	1,093	73.5%
Henderson	238	16.4%	242	16.5%	245	16.5%
Subtotal	**1,309**	**90.0%**	**1,324**	**90.1%**	**1,338**	**90.0%**
In-migration	145	10.0%	147	10.0%	149	10.0%
Total	**1,455**	**100.0%**	**1,471**	**100.1%**	**1,487**	**100.0%**

*Source: Section III.1(a), page 58, and Exhibit 16, Table 5.
**Totals may not foot due to rounding.

However, the applicant provides inconsistent information regarding projected in-migration for the Mission GI South campus. In Section III.1(b), page 58, the applicant states it assumes that *"...10% of the GI endoscopy procedures at Mission GI South will come from other Buncombe County and Henderson zip codes and other counties."* But in the Pro Forma Section of the application, and also in Exhibit 16, Table 5, the applicant projects that in-migration at Mission GI South will be 15%. [See *Utilization Assumptions and Methodology* section of Criterion (3) and Criterion (5) for additional discussion, and Exhibit 16, Table 5 of the application.]

In Section III.1(a), page 56, the applicant projects that 70% of Mission Hospital's existing GI endoscopy volume originating from Buncombe and Henderson counties will shift to Mission GI South. In other words, 85-90% of the population that the applicant proposes to serve at the new Mission GI South campus represents a shift of existing GI endoscopy patients at Mission Hospital who reside in Buncombe and Henderson counties but who are currently traveling to Mission Hospital in Asheville for GI endoscopy services.

However, the applicant does not adequately indentify where the patients included in either the 10% or 15% in-migration will come from. Therefore, the applicant did not adequately identify the population to be served.

Demonstration of Need for the Proposed Project

Mission Hospital, Inc. operates six licensed GI endoscopy rooms on its main campus, located at 509 Biltmore Avenue in Asheville (Buncombe County). The applicant proposes to relocate one of its existing GI endoscopy rooms to a new medical office building in Fletcher. The relocated GI endoscopy room, to be known as *Mission GI South*, will be licensed as part of the hospital. Consequently, the applicant does not propose to develop a new health service facility. Specifically, a new ambulatory surgical facility.

Regarding the need for the proposed project, in Section II.6, page 12, the applicant states,

> *"The proposed relocation of one licensed GI endoscopy room from the Mission Campus to Mission GI South will expand access and choice for residents of the rapidly growing population of southern Buncombe County who require outpatient GI endoscopy services as well as all residents of Buncombe and surrounding counties that choose ease of service, parking, and access, provided by a convenient outpatient location. Currently, patients travel to downtown Asheville to receive outpatient GI endoscopy services on the Mission Campus. The Mission Campus is located in central Asheville in mountainous terrain. The existing campus is landlocked and has numerous parking decks and large facilities. Mission GI South in southern Buncombe County is desirable to health care consumers and physicians in the community because it will provide high quality patient care in a location that is convenient and easily accessible."*

In Section III.1(a), pages 21-43, the applicant further describes the need for the proposed project. The applicant states,

> *"The proposed project involves the relocation of an existing licensed GI endoscopy room from the Memorial Building of Mission Hospital Asheville to Mission GI South in southern Buncombe County, near the Town of Fletcher. The proposed project will establish a convenient, easily accessible, ambulatory setting in southern Buncombe County and is substantiated by the following reasons:*
>
> - *Prevalence of Gastrointestinal Disorder*
> - *Importance of Early Detection of Colorectal Cancer*
> - *Colon Cancer Screening Rates – Room for Improvement*
> - *Outpatient Colonoscopy Procedure Rates – National Survey of Ambulatory Surgery, United States, 1996 and 2006*
> - *Utilization of Existing GI Endoscopy Resources*

- *Population Growth in Buncombe and Surrounding Counties*
- *Growth and Development in Buncombe County*
- *Growth and Development in Fletcher, NC"*

Prevalence of Gastrointestinal Disorder

On page 21, the applicant states,

> *"A 2005 national study reported in Clinical Gastroenterology and Hepatology Volume 3, Issue 6, Pages 543-552 (June 2005) concluded that 44.9% of US adults had gastrointestinal symptoms over a three month period...Outpatient GI endoscopy is a major tool in determining underlying disease issues for many of these GI disorders."*

Importance of Early Detection of Colorectal Cancer

On page 23, the applicant states,

> *"Each year more than 145,000 people are diagnosed with colorectal cancer, often referred to as colon cancer, in the U.S. and almost 50,000 people die from it annually. The disease, however, is largely preventable with regular screening and is treatable with early detection."*

Further, on pages 26-28, the applicant states,

> *"Screening can find non-cancerous colorectal polyps and remove them before they become cancerous. If colorectal cancer does occur, early detection and treatment dramatically increase chances of survival.*
>
> *The relative 5-year survival rate for colorectal cancer when diagnosed at an early stage before it has spread is about 90%. But only about 4 out of 10 colorectal cancers are found at that early stage. Once the cancer has spread to nearby organs or lymph nodes, the 5-year relative survival rate goes down, and if cancer has spread to distant organs (like the liver or lung) the rate is about 11%.*
>
> ...
>
> *Not only does colorectal cancer screening save lives, but it also is cost effective. Studies have shown that the cost-effectiveness of colorectal screening is consistent with many other kinds of preventive services and is lower than some common interventions. It is much less expensive to remove a polyp during screening than to try to treat advanced colorectal cancer. With sharp cost increases possible as new treatments become standards of care, screening is likely to become even more cost effective.*

...

Colonoscopy, which provides the most comprehensive view of the colon, is the definitive test for colorectal cancer screening. Colonoscopies allow gastroenterologists to view the entire colon and rectum for polyps or cancer and during the same exam remove pre-cancerous polyps. It is the test most gastroenterologists recommend as the single best screening exam for colorectal cancer. It is the only method that combines both screening and prevention (by removal of pre-cancerous polyps)."

Colon Cancer Screening Rates

On page 29, the applicant states,

"More Americans are getting the message that colorectal cancer screening is important. Researchers from the National Cancer Institute and the University of Texas, Houston, say screening rates have increased among men and women over the past few years. But the rates still aren't where they need to be, experts say."

Outpatient Colonoscopy Procedure Rates – National Survey of Ambulatory Surgery, United States, 1996 and 2006

On page 29, the applicant states,

"The National Survey of Ambulatory Surgery, United States, 1996 and 2006 found that the majority of colonoscopies (up to 90% in 2006) take place in ambulatory settings compared with inpatient facilities. Mission GI South will provide an alternative ambulatory location for Mission patients in the southern market for GI endoscopies."

Utilization of Existing GI Endoscopy Resources

On page 31-34, the applicant states,

"Mission is the largest hospital in western North Carolina and serves as the tertiary care provider for the region. The following table shows Mission's GI endoscopy volume over the last three calendar years which is sufficient to justify all six of the existing licensed GI endoscopy rooms at Mission.

Mission Hospital
GI Endoscopy Volume
January 2008 – December 2010

	CY 2008		CY 2009		CY 2010	
	Cases	Procedures	Cases	Procedures	Cases	Procedures
Inpatient	2,577	3,538	2,632	3,696	2,531	3,699
Outpatient	4,249	5,156	4,120	5,116	3,982	4,692
Total	6,826	8,694	6,752	8,812	6,513	8,661
GI Endo Rooms Needed at 1,500 procedures/yr		6		6		6
Procedures per Case		1.27		1.31		1.33

Source: Exhibit 16, Table 2

Importantly, as shown in the previous table, GI endoscopy procedures have remained flat over the last three calendar years. Inpatient procedures at Mission are at a three-year high. Furthermore, procedure growth has resulted in a higher GI endoscopy procedure to case ratio at Mission.

GI endoscopy volumes provided by the two existing GI endoscopy providers in Buncombe County, Mission Hospital and The Endoscopy Center, are sufficient to support 15.6 GI endoscopy rooms, as shown in the following table.

Buncombe County Providers
GI Endoscopy Volume
October 2007 – September 2010

Buncombe County	*FY 2008*		*FY 2009*		*FY 2010*	
	Cases	*Procedures*	*Cases*	*Procedures*	*Cases*	*Procedures*
Mission Hospital IP GI Endoscopy	*2,577*	*3,538*	*2,632*	*3,696*	*2,531*	*3,699*
Mission Hospital OP GI Endoscopy	*4,249*	*5,156*	*4,120*	*5,116*	*3,982*	*4,962*
Total Mission Hospital	*6,826*	*8,694*	*6,752*	*8,812*	*6,513*	*8,661*
The Endoscopy Center OP GI Endoscopy	*10,448*	*14,370*	*11,129*	*14,982*	*10,980*	*14,765*
Total GI Endoscopy Performed in Buncombe County	*17,274***	*23,064***	*17,881***	*23,794***	*17,493***	*23,426***
GI Endoscopy Rooms Needed at 1,500 procedures/yr		*15.4*		*15.9*		*15.6*
2010 Licensed GI Endoscopy Inventory		*11.0*		*11.0*		*11.0*
Additional GI Endoscopy Rooms Needed		*4.4*		*4.9*		*(4.6)*

[Emphasis in original.]
Source: Exhibit 16, Table 7
**Mission has 6 licensed GI endoscopy rooms; The Endoscopy Center has 5 licensed GI endoscopy rooms*
**The Project Analyst gets slightly different numbers for the total number of GI endoscopy cases and procedures performed in Buncombe County than what the applicant provided, based on data in the 2009 – 2011 State Medical Facilities Plans (SMFPs). The total number of cases and procedures provided by the applicant for Mission Hospital differs from the data in the 2009 – 2011 SMFPs. The total number of cases and procedures in Buncombe County, based on the SMFPs is as follows: FFY 2008: 17,512 cases and 23,312 procedures; FFY 2009: 17,870 cases and 23,517 procedures; FFY 2010: 17,643 cases. The total # of procedures in FFY 2010 matches what is provided in the 2011 SMFP.

As shown in the previous table, 4.6 additional GI endoscopy rooms could be developed in Buncombe County based upon FY 2010 GI endoscopy procedures provided in the county.

Mission GI South will provide improved access for the significant number of residents from south Buncombe County and Henderson County that currently choose to seek care at Mission and The Endoscopy Center in Buncombe County. Gastroenterologists associated with The Endoscopy Center are supportive of the proposed Mission GI South as reflected in letters of support in Exhibit 10.

Furthermore, the proposed relocated GI endoscopy room will not negatively impact existing GI endoscopy providers in either Buncombe or Henderson Counties as current GI endoscopy utilization in the two counties combined is sufficient to justify all seventeen licensed GI endoscopy rooms in each of the last three fiscal years. Even though GI endoscopy volumes have been flat current volume continues to justify all existing GI endoscopy rooms as shown in the following table.

Buncombe and Henderson Counties Providers
GI Endoscopy Volume
October 2007 – September 2010

GI Endoscopy Provider	FY 2008	FY 2009	FY 2010
Mission Hospital			
Cases	7,050	6,724	6,550
Procedures	9,032	8,673	8,714
The Endoscopy Center			
Cases	10,448	11,129	10,980
Procedures	14,370	14,982	14,765
Carolina Mountain Endoscopy Center			
Cases	3,541	2,551	3,283
Procedures	3,646	3,316	3,475
Pardee Hospital			
Cases	3,891	3,427	2,511
Procedures	4,562	4,289	4,090
Park Ridge Hospital			
Cases	762	649	676
Procedures	970	No data	No data
Total			
Cases	25,692	24,480	24,000
Procedures	32,580	31,260	31,044
GI Endoscopy Rooms Needed at 1,500 Procedures/Year	21.7	20.8	20.7
Licensed GI Endoscopy Rooms	17	17	17
Surplus (+) / Deficit (-)	-4.7	-3.8	-3.7

[Emphasis in original.]
Source: Exhibit 16, Table 8
There are 11 licensed GI endoscopy rooms in Buncombe County, and 6 licensed GI endoscopy rooms in Henderson County.

As shown in the previous table, there is sufficient GI endoscopy volume in the two county area for 3.7 additional GI endoscopy rooms in the most recent fiscal year."

Population Growth in Buncombe and Surrounding Counties

On pages 35-36, the applicant states,

> *"Population growth in Buncombe and surrounding counties, especially for the population over the age of 55, is experiencing steady growth. Total population by county and population for the age cohort of 55+ were obtained from the North Carolina Office of State Budget and Management (NC OSBM). Total projected population growth from 2010 to 2015 for counties in the Mission Hospital GI Endoscopy Service Area is shown in the following table.*

Mission Hospital
GI Endoscopy Service Area
Projected Population All Ages 2010-2015

County	2010	2015	2010-2015 CAGR
Primary Service Area			
Buncombe	233,999	248,638	1.2%
Secondary Service Area			
Henderson	107,383	116,216	1.6%
McDowell	45,717	48,631	1.2%
Haywood	57,695	58,960	0.4%
Madison	21,314	22,537	1.1%
Subtotal	232,109	246,344	1.2%
Tertiary Service Area			
Yancey	18,901	19,675	0.8%
Transylvania	31,647	32,868	0.8%
Mitchell	16,073	16,208	0.2%
Jackson	38,096	40,859	1.4%
Macon	35,468	38,475	1.6%
Cherokee	27,874	29,733	1.3%
Burke	91,355	96,599	1.1%
Swain	14,305	15,109	1.1%
Subtotal	273,719	289,526	1.1%
Total	739,827	784,508	1.2%

Source: Exhibit 16, Table 13

As shown in the previous table, the population of Buncombe County is expected to grow at a compound annual rate of 1.2% between 2010 and 2015, from 233,999 residents to 248,638 residents by 2015. The population of the four Secondary Service Area counties is projected to grow from 232,109 residents in 2010 to 246,344 residents by 2015, a compound annual growth rate of 1.2%. The population of the Tertiary Service Area is expected to grow from 273,719 in 2010 to 289,526 in 2015. Total Service Area population is estimated to be 739,827 and is projected to be 784,508 by 2015, which is growing at a compound annual rate of 1.2%.

The segment of the population ages 55 and older is growing at a much faster rate than the total population. Population trends in that age cohort are significant, as the average age to develop colorectal cancer is 70 years, and 93% of cases occur in persons 50 years of age or older. Current recommendations are to begin screening at age 50 if there are no risk factors other than age for colorectal cancers. A person whose only risk factor is their age is said to be at average risk.

Total projected population growth for the 55+ population from 2010 to 2015 for counties in the Mission Hospital Service Area is shown in the following table.

Mission Hospital
GI Endoscopy Service Area
Projected Population Ages 55+ 2010-2015

County	2010	2015	2010-2015 CAGR
Primary Service Area			
Buncombe	68,644	76,986	2.3%
Secondary Service Area			
Henderson	38,729	42,937	2.1%
McDowell	13,177	14,343	1.8%
Haywood	20,914	22,434	1.4%
Madison	6,707	7,285	1.7%
Subtotal	79,467	86,999	1.8%
Tertiary Service Area			
Yancey	6,670	7,176	1.5%
Transylvania	12,482	13,630	1.8%
Mitchell	5,635	5,923	1.0%
Jackson	11,527	12,813	2.1%
Macon	14,072	15,492	1.9%
Cherokee	11,255	12,613	2.3%
Burke	25,701	28,013	1.7%
Swain	4,267	4,720	2.0%
Subtotal	91,609	100,380	1.8%
Total	239,720	264,365	2.0%

Source: Exhibit 16, Table 14

As shown in the previous table, in the Primary Service Area, the 55+ population is expected to grow from 68,644 residents currently to 76,986 residents by 2015, a compound annual growth rate of 2.3%, more than twice the rate for the total projected population of Buncombe County. The Secondary and Tertiary Service Areas also are expected to experience growth in the 55+ population between 2010 and 2015, with the secondary service area growing at a compound annual rate of 1.8% and the Tertiary Service Area growing at a compound annual rate of 1.8%. The 55+ population of the entire Service Area is expected to increase from 239,720 in 2010 to 264,365 in 2015, representing an increase of 2.0% compounded annually. That trend reflects the general aging of the population seen nationally, as well as the fact that western North Carolina is a popular retirement destination. Those population estimates are conservative in that they do not include all retirees, who often have more than one residence."

Growth in Development in Buncombe County and Fletcher, NC

On pages 38-43, the applicant describes the attractiveness of Buncombe County and Fletcher, NC to prospective residents and businesses. Specifically, the applicant describes the following:

- Economic development
- Affordable housing
- Community transportation
- Planned infrastructure improvement

Utilization Assumptions and Methodology

The following table illustrates the historical and projected utilization for Mission Hospital GI endoscopy services through Project Year 3, as provided by the applicant in Section IV.1, page 76:

	Prior Full Year CY 2009	Last Full Year CY 2010	Interim Full Year CY 2011	Interim Full Year CY 2011	Project Year 1 CY 2013	Project Year 2 CY 2014	Project Year 3 CY 2015
# of Dedicated GI Endoscopy Rooms – Mission Campus	6	6	6	6	5	5	5
# of GI Endoscopy Procedures	8,812	8,661	8,645	8,628	7,157	7,125	7,092
# of Dedicated GI Endoscopy Rooms – Mission GI South	0	0	0	0	1	1	1
# of Outpatient GI Endoscopy Procedures – Mission GI South	0	0	0	0	1,455	1,471	1,487
Total # of Dedicated GI Endoscopy Rooms – Mission Hospital and Mission GI South	6	6	6	6	6	6	6
Total # of GI Endoscopy Procedures – Mission Hospital and Mission GI South	8,812	8,661	8,645	8,628	8,612	8,595	8,579

As illustrated in the table above, the applicant projects to perform a total of 8,595 procedures in six licensed GI endoscopy rooms, or 1,433 procedures per room (8,595 procedures / 6 rooms = 1,433 procedures) in Project Year 2 (CY 2014). While The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities [10A NCAC 14C .3900] requires a minimum performance threshold of 1,500 procedures per room, the Criteria and Standards are not applicable to this review because the applicant is not proposing to establish a new ambulatory surgical facility to be operated independently of the hospital. Rather, the applicant proposes to relocate one existing GI endoscopy room to another location and continue to operate it under Mission Hospital's license. Thus, the fact that the applicant projects to perform less than 1,500 procedures per room in Year 2 is not an issue for this application. (The applicant's use of the 1,500 procedures per room minimum performance threshold

throughout the application is for reference purposes only.) Mission Hospital already operates six licensed GI endoscopy rooms and is proposing to relocate one of the existing rooms from the main campus to another location in Fletcher, NC. In doing so, the applicant proposes to serve existing patients who live in southern Buncombe and northern Henderson Counties, and who are currently traveling to Mission Hospital for endoscopy services, thereby providing care to them closer to their homes.

In Section III.1(b), pages 44-59, the applicant provides the following methodology and assumptions used to project utilization:

Step 1: Determine Base Volume for Use in Projections

On page 45, the applicant provides historical utilization data for Mission Hospital's total GI endoscopy volume (inpatient and outpatient), as shown in the table below:

Mission Hospital
GI Endoscopy Volume
January 2008 – December 2010

	CY 2008		CY 2009		CY 2010	
	Cases	Procedures	Cases	Procedures	Cases	Procedures
Inpatient	2,577	3,538	2,632	3,696	2,531	3,699
Outpatient	4,249	5,156	4,120	5,116	3,982	4,962
Total	6,826	8,694	6,752	8,812	6,513	8,661

Source: Exhibit 16, Table 2

The data provided in the table above is from the hospital's internal Trendstar database. The applicant states that Trendstar data was used because it is the most current. On page 45, the applicant provides a comparison of its Trendstar data with License Renewal Application (LRA) data to demonstrate consistency. Over the three years of data provided for comparison (FY 2008 – FY 2010), the largest variance in the number of cases was 0.3% in FY 2009 and the largest variance in the number of procedures was 1.6%, also in FY 2009. Thus, the applicant does demonstrate that the Trendstar data is generally consistent with the LRA data. More specifically, regarding the decision to use Trendstar data, on pages 44-45, the applicant states,

> *"Mission reviewed and compared internal Trendstar for the most recent fiscal three years with the data reported in the 2009-2011 LRAs to assure the reliability of the internal database.*
>
> ...
>
> *...Mission's internal data is very consistent with the data reported on its Hospital License Renewal Applications in all three fiscal years. Therefore, Mission utilized the most current twelve months of data available as the base data for projections.*

...

Calendar year 2010 Trendstar data is the most current and reasonable data to use as a base to project future GI endoscopy utilization. It is also consistent with the project years, which are calendar year-based."

Step 2: Determine the Growth Rate for Projecting Total GI Endoscopy Utilization

The applicant reviewed historical GI endoscopy growth at Mission Hospital, population growth, and market trends to project the growth rate for total GI endoscopy utilization.

On page 46, the applicant provides historical GI endoscopy utilization at Mission Hospital for CY 2008 to CY 2010, and calculates procedures per case and the two-year Compound Annual Growth Rate (CAGR) for total inpatient and outpatient procedures, as shown below:

Mission Hospital
GI Endoscopy Volume
January 2008 – December 2010

	CY 2008		CY 2009		CY 2010		CAGR CY08-CY10	
	Cases	Procedures	Cases	Procedures	Cases	Procedures	Cases	Procedures
Inpatient	2,577	3,538	2,632	3,696	2,531	3,699	-0.9%*	2.3%*
Outpatient	4,249	5,156	4,120	5,116	3,982	4,962	-3.2%*	-1.9%*
Total	6,826	8,694	6,752	8,812	6,513	8,661	-2.3%*	-0.2%
Procedures per Case		1.27		1.31		1.33		

[Emphasis in original.]
Source: Exhibit 16, Table 2
*Calculated by the Project Analyst.

The applicant states,

"As shown in the previous table, procedures have remained flat, decreasing only slightly, during the last three calendar years. This is quite remarkable considering the development of freestanding outpatient GI endoscopy in North Carolina at the expense of hospital based GI endoscopy programs since the CON statute was amended to allow the development of freestanding GI centers in 2005. Inpatient GI endoscopy procedures at Mission Hospital reached a three-year high in CY 2010. Procedure growth at Mission has resulted in a higher GI endoscopy procedure to case ratio. ...

As previously discussed, Mission reasonably believes that GI endoscopy utilization has decreased due to the global economic crisis, beginning in December 2007, which gained intensity since September 2008. According to an

American Hospital Association survey the economic downturn is hitting hospitals hard as many patients struggle to pay their medial bills or put off care altogether. Nearly 60% of hospitals reported a moderate to significant decline in elective procedures compared with a year ago. Those numbers are similar to an Outpatient Surgery Magazine survey, also conducted in March 2009, in which 58% of readers said surgery volumes were down due to the struggling economy."

On page 47, the applicant provides patient origin data for total GI endoscopy services at Mission Hospital and calculates a weighted growth rate for GI endoscopy services, as shown in the table below:

Mission Hospital
Total GI Endoscopy Service Area
Weighted Population Growth Rate
Projected Population All Ages 2010-2015

County	*2010-2015 CAGR*	*FY 2010 GI Endoscopy Services Patient Origin*	*GI Endoscopy Services Weighted Growth Rate*
Formula	*A=County Specific CAGR*	*B=County Percent of Total Patient Origin*	*C=AxB*
Primary Service Area			
Buncombe	*1.2%*	*56.8%*	*0.7%*
Secondary Service Area			
Henderson	*1.6%*	*6.9%*	*0.1%*
McDowell	*1.2%*	*5.2%*	*0.1%*
Haywood	*0.4%*	*5.0%*	*0.0%*
Madison	*1.1%*	*4.6%*	*0.1%*
Tertiary Service Area			
Yancey	*0.8%*	*3.4%*	*0.0%*
Transylvania	*0.8%*	*2.4%*	*0.0%*
Mitchell	*0.2%*	*2.2%*	*0.0%*
Jackson	*1.4%*	*2.1%*	*0.0%*
Macon	*1.6%*	*1.9%*	*0.0%*
Cherokee	*1.3%*	*1.6%*	*0.0%*
Burke	*1.1%*	*1.4%*	*0.0%*
Swain	*1.1%*	*1.0%*	*0.0%*
*North Carolina**	*1.7%*	*5.5%*	*0.1%*
Mission Hospital Weighted Population Growth Rate = Sum of Column C			*1.2%*

Source: Exhibit 16, Table 13
Methodology = Sum of Individual County Growth Rates x County Specific Patient Origin
**All Other In-migration grown at NC State Growth Rate*

The table above shows a total weighted population growth rate of 1.2% for total GI endoscopy services (inpatient and outpatient) at Mission Hospital.

The applicant states,

"As discussed in Section III.1.(a) above, Mission reasonably expects that patients 55+ will continue to represent a greater percentage of GI endoscopy patients at Mission Hospital. Therefore, Mission also determined the weighted population growth rate for the 55+ population, as shown in the following table.

Mission Hospital
Total GI Endoscopy Service Area
Weighted Population Growth Rate
Projected Population Ages 55+ 2010-2015

County	*2010-2015 CAGR*	*FY 2010 GI Endoscopy Services Patient Origin*	*GI Endoscopy Services Weighted Growth Rate*
Formula	*A=County Specific CAGR*	*B=County Percent of Total Patient Origin*	*C=AxB*
Primary Service Area			
Buncombe	*2.3%*	*56.8%*	*1.3%*
Secondary Service Area			
Henderson	*2.1%*	*6.9%*	*0.1%*
McDowell	*1.8%*	*5.2%*	*0.1%*
Haywood	*1.4%*	*5.0%*	*0.1%*
Madison	*1.7%*	*4.6%*	*0.1%*
Tertiary Service Area			
Yancey	*1.5%*	*3.4%*	*0.0%*
Transylvania	*1.8%*	*2.4%*	*0.0%*
Mitchell	*1.0%*	*2.2%*	*0.0%*
Jackson	*2.1%*	*2.1%*	*0.0%*
Macon	*1.9%*	*1.9%*	*0.0%*
Cherokee	*2.3%*	*1.6%*	*0.0%*
Burke	*1.7%*	*1.4%*	*0.0%*
Swain	*2.0%*	*1.0%*	*0.0%*
*North Carolina**	*2.8%*	*5.5%*	*0.2%*
Mission Hospital Weighted Population Growth Rate = Sum of Column C			*2.1%*

Source: Exhibit 16, Table 14
Methodology = Sum of Individual County Growth Rates x County Specific Patient Origin
**All Other In-migration grown at NC State Growth Rate*

As shown in the previous table, the segment of the population ages 55+ is growing at a faster rate than the total population. The previous table shows a total weighted population growth rate of 2.1% for GI Endoscopy Services at Mission for residents 55+."

Step 3: Project Total GI Endoscopy Procedures

Based on the applicant's weighted population growth analysis in Step 2, the applicant determined that it would use Mission Hospital's historical CAGR (CY 2008 to CY 2010) of -0.2% to project total GI endoscopy procedures (inpatient and outpatient) through Project Year 3 (CY 2015). On page 49, the applicant describes how it arrived at this conclusion. The applicant states,

"This rate is:

- *Considerably less than the projected (2010-2015) 55+ weighted population growth rate of 2.1% in Mission GI Endoscopy Service Area counties which is the expected rate that GI endoscopy will grow once the economy recovers.*
- *Considerably less than the projected (2010-2015) weighted population growth rate of 1.2% in Mission GI Endoscopy Service Area counties."*

On page 49, the applicant applied Mission Hospital's historical CAGR of -0.2% to the total number of GI endoscopy procedures performed at Mission Hospital in CY 2010 (from Step 1) and projected forward through Project Year 3 (CY 2015), as shown in the table below:

GI Endoscopy	*CY 2010*	*CY 2008-CY 2010 CAGR*	*CY 2011*	*CY 2012*	*CY 2013*	*CY 2014*	*CY 2015*
Procedures	*8,661*	*-0.2%*	*8,645*	*8,628*	*8,612*	*8,595*	*8,579*

Source: Exhibit 16, Table 3

Step 4: Project Total GI Endoscopy Cases

On page 50, the applicant applied the average procedures per case for CY 2010 (calculated in Step 2) to the projected number of procedures (calculated in Step 3) to determine the projected number of cases through Project Year 3 (CY 2015), as shown in the table below:

GI Endoscopy	*CY 2010*	*CY 2010 Average Procedures per Case*	*CY 2011*	*CY 2012*	*PY 1: CY 2013*	*PY 2: CY 2014*	*PY 3: CY 2015*
Procedures	*8,661*	*1.33*	*8,645*	*8,628*	*8,612*	*8,595*	*8,579*
Cases	*6,513*		*6,501*	*6,488*	*6,476*	*6,464*	*6,451*
GI Endoscopy Rooms Needed @ 1,500 procedures per room	*5.8*		*5.8*	*5.8*	*5.8*	*5.8*	*5.8*

Source: Exhibit 16, Table 3

The applicant states,

> *"As shown in the previous table, even though projected GI endoscopy volume at Mission is projected to remain relatively flat with a very slight reduction in cases and procedures, projected CY 2015 utilization reflects a continued need for all six of the existing GI endoscopy rooms in Buncombe County."*

Step 5: Determine GI Endoscopy Use Rates for Buncombe and Henderson Counties

On page 51, the applicant used historical endoscopy utilization data from 2008 and 2011 License Renewal Applications and county population data to calculate endoscopy use rates for residents of Buncombe and Henderson counties, as shown in the following table:

Total GI Endoscopy Use Rates
FY 2007 and FY 2010

Total GI Endoscopy	*Buncombe*	*Henderson*
FY 2007		
Cases	*11,682*	*5,689*
Population	*225,555*	*102,079*
Use Rates	*51.8*	*55.7*
FY 2010		
Cases	*11,484*	*6,245*
Population	*233,999*	*107,383*
Use Rate	*49.1*	*58.2*
Four Year Average		
Use Rate	*50.4*	*56.9*

[Emphasis in original.]
Source: Exhibit 16, Table 9

On page 51, the applicant states,

> *"In addition to 2007 and 2010 use rates, the previous table shows four year average use rates for each county. In Buncombe County GI utilization per 1,000 decreased slightly over the four year time frame. In Henderson County GI utilization per 1,000 increased slightly over the four year time frame. To adjust for anomalies across the timeframe, Mission utilized the county-specific four year average growth rate to project future GI utilization for Mission GI South zip service area."*

Step 6: Base Population for Mission GI South Service Area

The applicant has defined Mission GI South's service area as a nine zip-code service area within southern Buncombe and northern Henderson counties. In Section III.1(a), page 37, the applicant identifies the following nine-zip code service area for Mission GI South:

Mission GI South
Service Area
by Zip Code

Zip Code	County
28704	Buncombe
28803	Buncombe
28806	Buncombe
28732	Henderson
28742	Henderson
28758*	Henderson
28759	Henderson
28791	Henderson
28792	Henderson

*This zip code is a P.O. Box.

On page 52, the applicant provides the projected population growth for the nine zip-code service area, as shown in the table below:

Mission GI South
Service Area
Projected Population All Ages 2010-2015

County	*2010*	*2011*	*2012*	*2013*	*2014*	*2015*	*CAGR 2010-2015*
Combined Buncombe Zips	*80,717*	*81,536*	*82,363*	*83,199*	*84,043*	*84,896*	*1.0%*
Combined Henderson Zip[s]	*70,396*	*71,413*	*72,444*	*73,490*	*74,551*	*75,628*	*1.4%*
Total	*151,113*	*152,949*	*157,807*	*156,689*	*158,594*	*160,524*	*1.2%*

Source: Exhibit 16, Table 6

The applicant illustrates that the population in nine zip-code service area for all ages is projected to grow at a CAGR of 1.2% from CY 2010 to CY 2015.

Step 7: Project Outpatient GI Endoscopy Cases for Mission GI South Service Area

On page 53, the applicant projected the total number of GI endoscopy cases in the nine zip-code service area by multiplying the four-year average county-specific use rate (Step 5) by the projected population of the nine zip-code area (Step 6), as shown in the table below:

Mission GI South
Projected Total GI Endoscopy Cases in Service Area
2010-2015

Mission GI South	*2010*	*2011*	*2012*	*PY1: 2013*	*PY2: 2014*	*PY3: 2015*
Buncombe Zip Codes						
Zip Code Population	*80,717*	*81,536*	*82,363*	*83,199*	*84,043*	*84,896*
County GI Endoscopy Use Rate	*50.4*	*50.4*	*50.4*	*50.4*	*50.4*	*50.4*
Total Projected GI Endoscopy Cases	*4,071*	*4,112*	*4,154*	*4,196*	*4,239*	*4,282*
Henderson Zip Codes						
Zip Code Population	*70,396*	*71,413*	*72,444*	*73,490*	*74,551*	*75,628*
County GI Endoscopy Use Rate	*56.9*	*56.9*	*56.9*	*56.9*	*56.9*	*56.9*
Total Projected GI Endoscopy Cases	*4,009*	*4,067*	*4,125*	*4,185*	*4,245*	*4,307*

Source: Exhibit 16, Table 5

In Step 5, the applicant calculated a use rate based on the total number of GI endoscopy cases at Mission Hospital, as reported on its License Renewal Application. As such, the projected number of cases in the table above includes inpatient and outpatient cases. However, the proposed project is for outpatient GI endoscopy services only. Thus, on page 53, the applicant calculates the percentage of inpatient and outpatient cases for the Mission GI South service area. The applicant states,

> *"Mission analyzed internal Trendstar inpatient and outpatient GI endoscopy data for FYs 2008, 2009, and 2010 and combined those volumes with the FYs 2008, 2009, and 2010 outpatient volume reported by The Endoscopy Center, the other GI endoscopy provider located in Buncombe County. The following table summarizes the historical inpatient and outpatient GI endoscopy split for Buncombe County providers and calculates the three-year average inpatient outpatient split.*

Buncombe County
GI Endoscopy Cases – Inpatient and Outpatient Percentages
October 2007 – September 2010

Buncombe County	*FY 2008*		*FY 2009*		*FY 2010*		*Three Year Avg Inpt/Outpt Split*	
	Cases	*Procedures*	*Cases*	*Procedures*	*Cases*	*Procedures*		
Mission Hospital IP GI Endoscopy	*2,577*	*3,538*	*2,632*	*3,696*	*2,531*	*3,699*	*3,644*	*16%*
Mission Hospital OP GI Endoscopy	*4,249*	*5,156*	*4,120*	*5,116*	*3,982*	*4,962*		
The Endoscopy Center OP GI Endoscopy	*10,488*	*14,370*	*11,129*	*14,982*	*10,980*	*14,765*	*19,784*	*84%*
Total GI Endoscopy	*17,274*	*23,064*	*17,881*	*23,794*	*17,493*	*23,426*	*23,428*	*100%*

[Emphasis in original.]
Source: Exhibit 16, Table 7

Mission determined that outpatient GI endoscopy cases represented an average of 84% of combined Mission Hospital and The Endoscopy Center cases over the last three fiscal years, as shown in the previous table."

It should be noted that while the applicant refers to cases when describing the three-year average split, the Project Analyst determined that three-year averages shown in the table above (3,644 for Mission inpatient cases, 19,784 for Mission and The Endoscopy Center outpatient cases, and 23,428 for total cases) are actually the average procedures, not cases. The Project Analyst calculated the three-year average number of cases as 2,580 for Mission inpatient cases, 14,969 for Mission and The Endoscopy Center outpatient cases, and 17,549 for total cases. This results in a three-year average split of 15% for inpatient cases, and 85% for outpatient cases. Thus, the fact that the applicant calculated the three-year average split based on procedures rather than cases does not pose an issue for the methodology.

There are two GI endoscopy providers in Asheville – Mission Hospital and The Endoscopy Center. Mission Hospital performs inpatient and outpatient GI endoscopy procedures, and The Endoscopy Center performs only outpatient procedures. Regarding the inclusion of The Endoscopy Center's outpatient cases and procedures along with Mission Hospital's outpatient cases and procedures, on page 54, the applicant states the following:

"Rather than using solely the Mission inpatient/outpatient GI endoscopy split, Mission believes that the combined average better reflects the total outpatient GI endoscopy volume in [the] *Mission GI South Service Area since it will be an outpatient only location."*

It is reasonable for the applicant to include both Mission Hospital's outpatient utilization data and The Endoscopy Center's utilization data because it provides a more complete picture of total outpatient GI endoscopy utilization in Buncombe County.

On page 54, the applicant then multiplied the projected total number of GI endoscopy cases (inpatient and outpatient) in the Buncombe and Henderson County zip code service area (calculated earlier in this Step) by 84% to calculate the projected number of outpatient GI endoscopy cases in the Mission GI South service area, as shown in the table below:

Mission GI South Service Area
Projected Total Outpatient GI Endoscopy Cases
2010-2015

Mission GI South	*2010*	*2011*	*2012*	*PY1: 2013*	*PY2: 2014*	*PY3: 2015*
Buncombe Zip Codes						
Total Projected GI Endoscopy Cases	*4,071*	*4,112*	*4,154*	*4,196*	*4,239*	*4,282*
Percent OP GI Endoscopy	*84%*	*84%*	*84%*	*84%*	*84%*	*84%*
Projected OP GI Endoscopy Cases	*3,438*	*3,473*	*3,508*	*3,543*	*3,579*	*3,616*
Henderson Zip Codes						
Total Projected GI Endoscopy Cases	*4,009*	*4,067*	*4,125*	*4,185*	*4,245*	*4,307*
Percent OP GI Endoscopy	*84%*	*84%*	*84%*	*84%*	*84%*	*84%*
Projected OP GI Endoscopy Cases	*3,385*	*3,434*	*3,484*	*3,534*	*3,585*	*3,637*

Source: Exhibit 16, Table 5

As shown in the table above, the applicant projects a total of 7,253 outpatient endoscopy cases (3,616 + 3,637 = 7,253) in the Mission GI South service area by the third year of the project (CY 2015).

On page 54, the applicant states,

> *"The previous table reflects projected outpatient GI endoscopy cases in the Service Area zip codes in Buncombe and Henderson Counties for all residents of* [the] *Mission GI South Service Area. Because inpatient GI endoscopy data was not publically available for Henderson County, the Buncombe County inpatient/outpatient split was used as a proxy. Both counties are known as retirement locations with over 30% of the population aged 55 and over, and Henderson is rapidly becoming more urban as Asheville expands south."*

The applicant correctly stated that inpatient GI endoscopy data was not publically available for Henderson County. The publicly-available License Renewal Application form does not separate inpatient and outpatient GI endoscopy procedures. Only the total number of GI endoscopy procedures is collected. Therefore, given the geographic proximity and demographic similarities of Buncombe and Henderson Counties, as noted by the applicant, the use of the Buncombe County outpatient GI endoscopy cases as a proxy for Henderson County GI endoscopy cases is reasonable.

Step 8: Calculate Outpatient GI Endoscopy Procedures in Mission GI South Service Area

Based on the historical experience of Mission Hospital, the applicant calculated that Mission Hospital performed 1.33 procedures per case in CY 2010 (see page 31 of the application). On page 55, the applicant multiplied the 1.33 procedures per case ratio by the total projected GI endoscopy cases in the Mission GI South service area (Step 7) to determine the projected number of procedures in Mission GI South service area, as shown in the following table:

Mission GI South Service Area
Projected Outpatient GI Endoscopy Procedures
2010-2015

Mission GI South	*2010*	*2011*	*2012*	*PY1: 2013*	*PY2: 2014*	*PY3: 2015*
Buncombe Zip Codes						
Projected OP GI Endoscopy Cases	*3,438*	*3,473*	*3,508*	*3,543*	*3,579*	*3,616*
Procedures per Case	*1.33*	*1.33*	*1.33*	*1.33*	*1.33*	*1.33*
Projected OP GI Endoscopy Procedures	*4,571*	*4,618*	*4,665*	*4,712*	*4,760*	*4,808*
Henderson Zip Codes						
Projected OP GI Endoscopy Cases	*3,385*	*3,434*	*3,484*	*3,534*	*3,585*	*3,637*
Procedures per Case	*1.33*	*1.33*	*1.33*	*1.33*	*1.33*	*1.33*
Projected OP GI Endoscopy Procedures	*4,501*	*4,566*	*4,632*	*4,699*	*4,767*	*4,836*

Source: Exhibit 16, Table 5

As shown in the table above, the applicant projects a total of 9,644 outpatient endoscopy procedures (4,808 + 4,836 = 9,644) in the Mission GI South service area by the third year of the project (CY 2015).

Step 9: Determine Mission Hospital Market Share of Total GI Endoscopy Cases in Buncombe and Henderson Counties

On pages 55 and 56, the applicant used 2008 and 2011 License Renewal Application (LRA) data to determine Mission Hospital's market share of total GI endoscopy cases (inpatient and outpatient) in Buncombe and Henderson counties, as shown in the following two tables:

Mission Hospital
Market Share of Total GI Endoscopy Cases in Buncombe County
FY 2007 and FY 2010

Provider	*2007*		*2010*	
	Cases	*Percent*	*Cases*	*Percent*
Margaret R. Pardee Memorial Hospital	*113*	*1.0%*	*76*	*0.7%*
The Endoscopy Center	*6,515*	*55.8%*	*6,958*	*60.6%*
Park Ridge Hospital	*282*	*2.4%*	*133*	*1.2%*
Mission Hospital	*4,561*	*39.0%*	*3730*	*32.5%*
Carolina Mountain Gastroenterology Endoscopy Center	*9*	*0.1%*	*297*	*2.6%*
Transylvania Community Hospital and Bridgeway	*5*	*0.0%*	*5*	*0.0%*
All Other	*197*	*1.7%*	*285*	*2.5%*
Total	*11,682*	*100.0%*	*11,484*	*100.0%*

[Emphasis in original.]
Source: Exhibit 16, Table 10

Mission Hospital
Market Share of Total GI Endoscopy Cases in Henderson County
FY 2007 and FY 2010

Provider	2007		2010	
	Cases	Percent	Cases	Percent
Margaret R. Pardee Memorial Hospital	3,283	57.7%	2,100	33.6%
The Endoscopy Center	942	16.6%	1,003	16.1%
Park Ridge Hospital	731	12.8%	454	7.3%
Mission Hospital	509	8.9%	452	7.2%
Carolina Mountain Gastroenterology Endoscopy Center	102	1.8%	2,063	33.0%
Transylvania Community Hospital and Bridgeway	53	0.9%	49	0.8%
All Other	69	1.2%	124	2.0%
Total	5,689	100.0%	6,245	100.0%

[Emphasis in original.]
Source: Exhibit 16, Table 11

Regarding Mission Hospital's market share in Buncombe County, on page 56, the applicant states,

> *"The previous table shows that Mission's market share of Buncombe County GI endoscopy decreased from FY 2007 and FY 2010 as a result of the shift in patients to The Endoscopy Center and the new outpatient GI center in Henderson County. In addition, GI endoscopy volume has declined due to an economic downturn and a shift in that volume to community settings as previously discussed."*

Regarding Mission Hospital's market share in Henderson County, on page 56, the applicant states,

> *"The previous table shows that Mission has lost some market share in Henderson County from FY 2007 to FY 2010 as outpatient GI endoscopy volume has shifted to Carolina Mountain Gastroenterology Endoscopy Center, which entered the Henderson County market in FY 2007."*

Step 10: Project Mission GI South Outpatient GI Endoscopy Procedures

The applicant assumes that Mission GI South will capture 70% of Mission Hospital's existing market share for Buncombe and Henderson counties in FY 2010, which was calculated in Step 9 to be 32.5% in Buncombe County and 7.2% in Henderson County. In other words, the applicant assumes 70% of its existing GI endoscopy patients from the Mission GI South service area will shift to the Mission GI South campus from the Asheville campus. On pages 56-57, the applicant states,

"While it is reasonable to assume that 100% of outpatient cases could shift to the new outpatient location for improved access in an outpatient setting, some cases may be more complex or patients could have co-morbidities [sic] *may choose to go to the Mission campus in Asheville. However, over 80% of all cases reviewed were cases routinely performed in outpatient GI Centers. Therefore, a target of 70% was determined to be reasonable. Mission GI South's resulting market share of Mission GI South Service Area was calculated as follows:*

- *Service Area Zip Codes in Buncombe County: 70% of Buncombe County market share of 32.5% = 22.7%*
- *Service Area Zip Codes in Henderson County: 70% of Henderson County market share of 7.2% = 5.1%*

For purposes of this Application, Mission assumes that the projected procedures performed at Mission GI South would be performed at Mission if the project were not developed. However, it is possible that cases from other providers in Buncombe County may shift to the proposed facility as the physicians associated with Asheville Gastroenterology Associates (AGA), who own and operate The Endoscopy Center, are very supportive of the proposed project as evidenced in the letters of support included in Exhibit 10. Furthermore, in 2010 over 1,000 patients from Henderson County received outpatient GI endoscopy procedures at The Endoscopy Center. Mission GI South would provide a more accessible alternative for these patients of AGA.

In addition, as the economy improves and GI endoscopy procedures begin to increase, some percent of cases at Mission GI South will result from the growth in the south Buncombe geographic area. As previously discussed this is one of the fastest growing areas in Buncombe and Henderson Counties. As a result, Mission believes the market share projections are reasonable to use in determining future volume performed at Mission GI South."

On page 57, the applicant projected the number of outpatient GI endoscopy procedures at Mission GI South through the third year of the project by multiplying the county-specific market share percentages described above by the projected number of outpatient GI endoscopy procedures at Mission GI South from Step 8, as shown below:

Mission GI South
Projected Outpatient GI Endoscopy Procedures
2010-2015

Mission GI South	*2010*	*2011*	*2012*	*PY1: 2013*	*PY2: 2014*	*PY3: 2015*
Buncombe Zip Codes						
Expected GI Endoscopy Procedures	*4,571*	*4,618*	*4,665*	*4,712*	*4,760*	*4,808*
Projected Market Share – Mission GI South	*22.7%*	*22.7%*	*22.7%*	*22.7%*	*22.7%*	*22.7%*
Projected OP GI Endoscopy Procedures – Mission GI South	*1,039*	*1,050*	*1,061*	*1,071*	*1,082*	*1,093*
Henderson Zip Codes						
Expected GI Endoscopy Procedures	*4501*	*4566*	*4632*	*4669*	*4767*	*8836*
Projected Market Share – Mission GI South	*5.1%*	*5.1%*	*5.1%*	*5.1%*	*5.1%*	*5.1%*
Projected OP GI Endoscopy Procedures – Mission GI South	*228*	*231*	*235*	*238*	*242*	*245*
Combined						
Projected OP GI Endoscopy Procedures – Mission GI South	*1,267*	*1,281*	*1,295*	*1,309*	*1,324*	*1,338*

Source: Exhibit 16, Table 5

In addition to the projected outpatient GI endoscopy procedures calculated in the table above, the applicant also projects that approximately 10% of the procedures performed at Mission GI South will be as a result of "in-migration." On page 58, the applicant states,

> *"Mission is cognizant that some patients will choose to travel a bit further from their homes to Mission GI South in order to forgo a trip to Mission Hospital in downtown Asheville. Mission conservatively projects that 10% of GI endoscopy procedures at Mission GI South will come from other Buncombe and Henderson zip codes and other counties, as shown in the following table. That assumption is supported by the geographic accessibility of Mission GI South and Mission's historical patient origin which reflects in-migration from counties other than Buncombe and Henderson to be over 34% as reflected in Exhibit 16, Table 12."*

Of the counties in Mission Hospital's secondary and tertiary service areas (see Exhibit 16, Table 2 and Section III.6, page 70), it is unreasonable to assume that patients from many of these counties would by-pass Mission Hospital and travel to Mission GI South, particularly counties that are north of Buncombe County, i.e. Madison, Yancey, and Mitchell. Moreover, the applicant does not specifically identify the counties and/or zip codes within Mission Hospital's existing service area from which it expects to see patients at Mission GI South. Thus, the project analyst could not validate the reasonableness of the applicant's 10% in-migration assumption (much less the 15% "in-migration" assumption) merely based on the fact that the in-migration rate at Mission Hospital from counties other than Buncombe and Henderson is 34%. "In-migration" at Mission Hospital includes inpatients as well as outpatients and Mission Hospital is a

tertiary hospital serving patients from a large geographic area. The service area for the proposed Mission GI South is not likely to be similar to the service area for Mission Hospital.

However, it is reasonable to assume that some patients from Mission Hospital's service area would travel to Mission GI South. The Project Analyst looked at Mission Hospital's patient origin by county for total GI endoscopy cases (inpatient and outpatient), as reported on its 2011 LRA, in conjunction with a map of the State of North Carolina. The Project Analyst determined that it is reasonable to assume that residents from the following counties (excluding Buncombe and Henderson counties) would seek outpatient GI endoscopy services at Mission GI South rather than traveling to Mission Hospital, based on geographic proximity to Mission GI South. (Note: Buncombe and Henderson counties are included here for reference purposes only.):

Mission Hospital
Total GI Endoscopy Patients
(Inpatient and Outpatient)

County	# of Total GI Endoscopy Patients	% of Total GI Endoscopy Patients
Buncombe	3,730	56.8%
Henderson	452	6.9%
Sub-total	4,182	63.7%
Transylvania	158	2.4%
Jackson	135	2.1%
Macon	127	1.9%
Polk	27	0.4%
Rutherford	60	0.9%
Sub-total	508	7.7%
Total # Endoscopy Patients at Mission Hospital	6,563	100.0%

*Source: 2011 LRA, page 37.

As shown in the table above, based on geographic proximity and the non-emergent nature of GI endoscopy services projected to be performed at Mission GI South, the Project Analyst identified five counties from which residents are likely to travel to Mission GI South rather than Mission Hospital for GI endoscopy services: Transylvania, Jackson, Macon, Polk, and Rutherford. Thus, the Project Analyst estimates a total of 508 patients or 7.7% of patients residing in counties outside of Buncombe and Henderson counties can be expected to seek GI endoscopy services at Mission GI South, based on the current patient origin for total GI endoscopy services at Mission Hospital. It is also important to note that Mission Hospital's historical patient origin for GI endoscopy services includes both inpatient and outpatient cases. As such, the 508 patients from these counties includes both inpatient and outpatient cases. Therefore, the percentage of patients receiving outpatient GI endoscopy services would make up an even smaller percent of

patients seeking GI endoscopy services at Mission GI South. Nevertheless, based on the Project Analyst's determination, the applicant's assumption of 10% in-migration at Mission GI South from counties outside of Buncombe and Henderson Counties is overstated.

On page 58, after factoring in in-migration, the applicant projects the total number of outpatient procedures at Mission GI South through Project Year 3, as shown in the following table:

Mission GI South
Total Projected Outpatient GI Endoscopy Procedures
2010 - 2015

Mission GI South	2010	2011	2012	PY1: 2013	PY2: 2014	PY3: 2015
Projected OP GI Endoscopy Procedures – Combined Buncombe & Henderson Zip Codes	1,267	1,281	1,295	1,309	1,324	1,338
In-migration (10%)				145	147	149
Total Projected OP GI Endoscopy Procedures				1,455	1,471	1,487
GI Endoscopy Rooms Needed at Mission GI South				1	1	1

Source: Section III.1(b), page 58.

As shown in the table above, the applicant projects to perform 1,455 outpatient GI endoscopy procedures at Mission GI South in Project Year 1, 1,471 in Project Year 2, and 1,487 in Project Year 3, assuming 10% in-migration. However, as previously noted in this section, projected in-migration for Mission GI South is overstated. Therefore, the projected number of procedures the applicant projects to perform at Mission GI South is overstated.

Additionally, the applicant provides inconsistent information regarding projected in-migration for Mission GI South. While the applicant states that 10% of the GI endoscopy procedures at Mission GI South will come from other Buncombe County and Henderson County zip codes and other counties, in the Pro Forma Section of the application, and also in Exhibit 16, Table 5, the applicant projects that in-migration at Mission GI South will be 15%. [See Criterion (5) for additional discussion.] Assuming 15% in-migration for Mission GI South results in the following projected utilization, as shown below:

Mission GI South
Total Projected Outpatient GI Endoscopy Procedures
2010 – 2015

Mission GI South	2010	2011	2012	PY1: 2013	PY2: 2014	PY3: 2015
Projected OP GI Endoscopy Procedures – Combined Buncombe & Henderson Zip Codes	1,267	1,281	1,295	1,309	1,324	1,338
In-migration (15%)				231	234	236
Total Projected OP GI Endoscopy Procedures				1,540	1,558	1,574
GI Endoscopy Rooms Needed at Mission GI South				1	1	1

Source: Exhibit 16, Table 5. Also see Pro Forma Section for Mission GI South's pro forma projections and the discussion in Criterion (5).

Thus, as shown in the two tables above, the in-migration information provided by the applicant for Mission GI South is inconsistent. The latter table shows that with 15% in-migration, the applicant projects to perform 1,540 outpatient GI endoscopy procedures in Project Year 1, 1,558 in Year 2, and 1,574 in Year 3, which is 85 more procedures in Project Year 1, 87 more in Year 2, and 87 in Year 3. Based on the differing information provided between the applicant's utilization and assumptions and the pro formas [Section II.1(b) of the application, Exhibit 16, Table 5, and the Pro Forma Section], the Project Analyst found the applicant's projected utilization assumptions to be unreliable. Therefore, projected utilization for Mission GI South is unreliable.

Need Analysis

Mission Hospital currently operates six licensed GI endoscopy rooms on its main campus in Asheville, in the northern portion of Buncombe County. The applicant proposes to relocate one of its existing GI endoscopy rooms to a new location in Fletcher, NC, in the southern portion of Buncombe County. The proposed new location will be called Mission GI South. The applicant does not propose to establish a new, separately licensed ambulatory surgical facility. Rather, the relocated GI endoscopy room will remain on the hospital's license. Indeed, Mission GI South can be thought of as a "satellite" GI endoscopy room of Mission Hospital. In Section III.1(b), the applicant states, *"The proposed satellite GI endoscopy room at Mission GI South is projected to become operational in January 2013."*

In Sections III.6 and III.7, pages 70 and 71, the applicant states that Buncombe and Henderson counties make up 63.7% of Mission Hospital's service area (Buncombe = 56.8% and Henderson = 6.9%). Within this service area, the applicant has identified a "sub-service area" for Mission GI South consisting of nine zip codes. The applicant states it proposes to serve existing Mission Hospital patients who live in the "sub-service area" and are currently traveling to the main campus in Asheville, thereby providing GI

endoscopy services to Mission's existing patients in a location closer to where they live.

In Section III.1(a), page 32, the applicant states, *"Mission GI South will provide improved access for the significant number of residents from south Buncombe County and Henderson County that currently choose to seek care at Mission and The Endoscopy Center in Buncombe County."* Additionally, in Section III.1(a), page 29, the applicant states, *"Mission GI South will provide an alternative ambulatory location for Mission patients in the southern market for GI endoscopies."*

As the relocated GI endoscopy room will remain on Mission Hospital's license and continue to be counted in the hospital's inventory of licensed GI endoscopy rooms, the applicant projected utilization at Mission GI South based on Mission Hospital's historical utilization of all six existing licensed GI endoscopy rooms. In Section III.1(b), page 46, the applicant illustrates that from CY 2008 to CY 2010, the total number of procedures (inpatient and outpatient) performed in the six existing licensed GI endoscopy rooms at Mission Hospital remained relatively flat, with a compound annual growth rate (CAGR) rate of -0.2% (or 0.0% when rounding) over the three-year period.

The number of GI endoscopy procedures has remained relatively flat not just at Mission Hospital, but for surrounding providers as well. In fact, the total number of procedures at the five existing GI endoscopy providers in Buncombe and Henderson counties has remained relatively flat or declined from FFY 2008 to FFY 2010. According to data in the 2009 to 2011 SMFPs, a total of 32,490 procedures were performed in Buncombe and Henderson counties in FFY 2008 and a total of 31,600 procedures were performed in FFY 2010. From FFY 2008 to FFY 2010, the CAGR in total procedures performed in Buncombe and Henderson counties was -1.38%.

There are 11 GI endoscopy rooms in Buncombe County. Mission Hospital has six rooms and The Endoscopy Center has five rooms, all of which are located in the northern portion of Buncombe County. Historical utilization of the 11 GI endoscopy rooms is illustrated below:

GI Endoscopy Room Utilization
Buncombe County

	FFY 2008	FFY 2009	FFY 2010	% Increase (Decrease)
# of Rooms	11	11	11	-
# of Cases	17,512	17,870	17,643	0.7%
# of Procedures	23,312	23,517	23,426	0.5%
# of Procedures per Room	2,119	2,138	2,130	-

*Source: 2009, 2010, 2011 State Medical Facilities Plans.

There are six GI endoscopy rooms in Henderson County. Carolina Mountain Gastroenterology Endoscopy Center has two rooms, Margaret R. Pardee Memorial Hospital has three rooms, and Park Ridge Hospital one room. Historical utilization of the six endoscopy rooms is illustrated below:

GI Endoscopy Room Utilization
Henderson County

	FFY 2008	FFY 2009	FFY 2010	% Increase (Decrease)
# of Rooms	6	6	6	-
# of Cases	8,194	6,627	6,403	(21.9%)
# of Procedures	9,178	8,254	8,174	(10.9%)
# of Procedures per Room	1,530	1,376	1,362	-

*Source: 2009, 2010, 2011 State Medical Facilities Plans.

As shown in the tables above, utilization in Buncombe County has remained relatively flat, as the number of cases and procedures have increased by just 0.7% and 0.5%, respectively, from FFY 2008 to FFY 2010.

Conversely, utilization in Henderson County has decreased, as the number of cases and procedures has decreased by 21.9% and 10.9%, respectively, over the same time period. In fact, the number of procedures performed per room in Henderson County's six GI endoscopy rooms in FFY 2010—1,362 procedures per room—is well below the threshold in The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities (10A NCAC 14C .3900) that requires a licensed GI endoscopy room to perform a minimum of 1,500 procedures per room. (By contrast, the number of procedures performed per room in Buncombe County's 11 GI endoscopy rooms in FFY 2010 was 2,130 procedures per room.)

Furthermore, while the applicant's utilization methodology assumes a -0.2% growth rate in the number of procedures through the project years, the growth in procedures in Henderson County has declined by 10.9% over the past two years. The applicant proposes to locate the proposed Mission GI South campus on the Buncombe/Henderson County line, where county-wide (Henderson County) GI endoscopy utilization is decreasing more rapidly than utilization in Buncombe County. Additionally, the six GI endoscopy rooms in Henderson County are in relative close proximity to the proposed Mission GI South campus—Park Ridge Hospital is approximately 5.15 miles; Carolina Mountain Gastroenterology Endoscopy Center is approximately 11.70 miles; and Margaret R. Pardee Memorial Hospital is approximately 11.80 miles. As can be seen in the previous table, Park Ridge Hospital (the facility in closest proximity to the proposed Mission GI South campus) performed the fewest number of GI endoscopy cases and procedures of the three Henderson County GI endoscopy providers. Park Ridge Hospital performed just 676 procedures per room[1] in FFY 2010—well below the threshold in The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities (10A NCAC 14C .3900) that requires a licensed GI endoscopy room to perform a minimum of 1,500 procedures per room. Thus, there is existing capacity for additional GI endoscopy procedures in the Mission GI South service area.

[1] In the 2011 and 2012 (Proposed) State Medical Facilities Plans (FFYs 2009 and 2010, respectively), Park Ridge is reported as performing 0 procedures. The CON Section assumes Park Ridge performed at least one procedure per case.

The applicant does not adequately demonstrate the need to locate one of its six existing GI endoscopy rooms on the Buncombe/Henderson County line (literally).

The applicant assumes that 70% Mission Hospital's Buncombe and Henderson County market shares for outpatient GI endoscopy will shift to Mission GI South due to better geographic access and convenience. It is also reasonable to assume that some patients from other counties outside of Buncombe and Henderson counties may utilize services at Mission GI South. However, the applicant's assumption that 10% of Mission GI South's patients will come from other counties outside of Buncombe and Henderson counties is unsupported. The applicant does not identify the counties or zip codes associated with the 10% in-migration assumption. The Project Analyst examined Mission Hospital's current patient origin for total GI endoscopy cases as provided in the 2011 LRA, along with a map of the State of North Carolina. Based on the counties where patients currently live, the information provided indicates that it is reasonable to expect only 7.7% in-migration at Mission GI South to come from counties outside of Buncombe and Henderson counties [See Assumptions and Methodology in Criterion (3) for additional discussion.] In Section III.1(a), page 53, the applicant states that in FY 2010, Mission Hospital had 2,531 inpatient cases and 3,982 outpatient cases. Thus, Mission Hospital's inpatient/outpatient split is 38.9% inpatient cases and 61.1% outpatient cases. As such, only a portion of the patients included in the applicant's projected in-migration rate would be expected to seek care in an outpatient setting. Therefore, the applicant overstates the projected utilization at Mission GI South.

Finally, the applicant provided inconsistent assumptions with regard to projected in-migration at Mission GI South. While the applicant assumes a 10% in-migration rate throughout the methodology in Section III of the application, the supporting data (Exhibit 16, Table 5) assumes a 15% in-migration rate. This discrepancy in and of itself would not be problematic but for the fact that the applicant assumes a 15% in-migration rate in the Mission GI South pro formas. [See Pro Forma Section and Criterion (5) for additional discussion.]

In conclusion, the applicant's methodology and assumptions for projecting utilization at Mission GI South overstates the number of GI endoscopy procedures projected to be performed because its in-migration assumptions are unsupported. Additionally, the applicant's methodology and assumptions are unreliable because the applicant provides inconsistent assumptions with regard to varying in-migration rates between the assumptions in Section III.1(b), page 58, Exhibit 16, Table 5, and the Pro Forma Section [See Criterion (5) for additional discussion]. Furthermore, the applicant does not adequately demonstrate the need to locate one of its six existing GI endoscopy rooms on the Buncombe/Henderson County line (literally) given the declining utilization in Henderson County and the existence of sufficient capacity in Henderson County.

In summary, the applicant did not adequately identify the population to be served and did not demonstrate the need that the population has for proposal. Therefore, the application is nonconforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate one of its existing six GI endoscopy rooms from Mission Hospital's main campus in Asheville to Fletcher, in Buncombe County. The relocated GI endoscopy room will be called Mission GI South, and will serve as a "satellite" location that will enable the applicant to provide care to patients who live in southern Buncombe County but are currently traveling to Mission Hospital. The Buncombe and Henderson County patients projected to be served at the relocated GI endoscopy room represent a shift of existing patients from Mission's main campus in Asheville to the new location in Fletcher, thereby providing these patients easier geographic access to services. Furthermore, with five GI endoscopy rooms remaining on the Mission Hospital campus upon completion of the proposed project, the applicant will have sufficient capacity to continue to serve existing and projected patients in Asheville. In Section IV.1(c), page 76, the applicant states that in CY 2010, Mission Hospital performed 8,661 procedures in six GI endoscopy rooms at its main campus in Asheville or 1,444 procedures per room (8,661 procedures / 6 rooms = 1,444 procedures per room). In CY 2015 (Project Year 3), the applicant projects to perform 7,092 procedures in the remaining five rooms in Asheville or 1,418 procedures per room (7,092 procedures / 5 rooms = 1,418 procedures per room). Therefore, the relocation of one GI endoscopy room will not result in the overutilization of the five remaining rooms in Asheville. Thus, patients who will continue to use the Asheville campus will not be affected by the relocation of one GI endoscopy room to Fletcher. Consequently, the application is conforming to this criterion.

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

In Section III.8, pages 71-72, the applicant describes the alternatives considered. The applicant considered developing a new GI endoscopy room rather than relocating one of the existing six rooms, but determined that it would be more reasonable to use existing resources. The applicant also considered relocating two rooms to southern Buncombe

County instead of one, but determined that the volume of existing cases originating from the southern portion of the county would not support two rooms.

The land and the MOB in which the relocated GI endoscopy room will operate straddle the Buncombe/Henderson County line. Exhibit 28 includes a copy of the warranty deed for the portion of the property in Buncombe County and a copy of the warranty deed for the portion of the property in Henderson County. Both deeds state the following, *"This deed is one of two deeds describing the above property, one being recorded in Buncombe County and one in Henderson County."* The majority of the property is located in Henderson County. Exhibit 28, page 508, includes an attachment to one of the warranty deeds describing the property as follows: *"Lying in Buncombe and Henderson Counties, being a tract of 7.739 acres, of which 2.735 acres are located in Buncombe County and 5.004 acres are located in Henderson County..."* Exhibit 29 includes a line drawing which shows that the county line crosses through the land and the MOB. Exhibit 6 includes a line drawing of the proposed GI endoscopy suite, which clearly shows that the county line cuts through the corner of the proposed space. Thus, as illustrated in the line drawings, the space in which the proposed relocated GI endoscopy room will be located is in both Buncombe and Henderson Counties.

In Section I.7 and I.8, the applicant states the physical address of the proposed relocated GI endoscopy room is 2651 Hendersonville Road in the Town of Fletcher, in Buncombe County. If the entire proposed GI endoscopy suite were located in Buncombe County there would be no change in the inventory of operating rooms in Buncombe County, as the GI endoscopy room being relocated is currently located in Buncombe County. However, due to the fact that a portion of the proposed GI endoscopy suite will be located in Henderson County, as illustrated in the line drawings provided by the applicant, the proposed project would arguably increase the inventory of licensed GI endoscopy rooms in Henderson County.

In Exhibit 29, the applicant provides a cost estimate from a registered architect for construction of the proposed project and related space in the medical office building (MOB). Mission Hospital already owns the land where the MOB will be located. The applicant states that a developer will own the building and Mission Hospital will lease space in the MOB for Mission GI South. However, the architect's cost estimate indicates there is a 60/40 ownership "adjustment" between the developer and Mission Hospital. However, the applicant does not provide enough information regarding the basis for determining that there will be a 60/40 ownership "adjustment" between the developer and Mission Hospital. Furthermore, it appears the developer should have been identified as a co-applicant in the application because the applicant does not adequately demonstrate that the developer will not be incurring an obligation for a capital expenditure which is a new institutional health service (i.e., developing space for a relocated GI endoscopy room in a licensed health service facility). Mission Hospital is the only applicant identified in the application. The applicant did not adequately demonstrate that the most effective alternative has been proposed to meet the need which the applicant states exists. See Criterion (3) for discussion regarding demonstration of need.

Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (12) and (18a). Therefore, the applicant did not adequately demonstrate that the proposal is its least costly or most effective alternative and the application is nonconforming with this criterion.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

NC

In Section VIII, page 99, the applicant states that the total capital cost is projected be $1,237,236, including $617,655 for construction costs and $619,581 for miscellaneous project costs, which consists of $567,911 for fixed equipment, $29,000 for furniture, and $17,120 for architectural and engineering fees. However, construction costs, fixed equipment, movable equipment, and furniture only add up to $614,031, as illustrated below:

Miscellaneous Project Costs	
Fixed Equipment	$567,911
Furniture	$29,000
Architectural and Engineering Fees	$17,120
Total Miscellaneous Project Costs	**$614,031**
*Difference***	*($5,550)*

*Source: Section VIII, page 99.
**Difference calculated as follows: $619,581 - $614,031 = $5,550.

Thus, in Section VIII, page 99, the applicant appears to overstate the total capital cost of the project by $5,550. However, it appears the developer will incur an obligation for a capital expenditure which is a new institutional health service. The capital cost reported by the applicant in Section VIII, page 99, does not include the 60% to be incurred by the developer. [In the letter from the certified architect included in Exhibit 29, the architect states that total building costs for the Mission GI South portion of the building will be $850,387, with the developer's ownership portion being 60% (or $510,232) and Mission Hospital's ownership portion being 40% (or $340,155).] If the developer's portion was included, the capital cost of the project would be $1,747,468 ($1,237,236 + $510,232 = $1,747,468). The applicant does not adequately demonstrate that the cost to be incurred by the developer should not be included. [See Criterion (4) for additional discussion.] Thus, the capital cost of the proposed project is understated.

In Section IX, page 106, the applicant projects there will be no start-up expenses associated with the project. While proposed to be licensed as part of the hospital, the relocated GI endoscopy room will be located on a new campus. It is not reasonable to

assume there will be no start-up expenses associated with development of a new campus, such as utilities or insurance.

Exhibit 26 contains a letter signed by a Senior Vice President, Finance and Chief Financial Officer at Mission Hospital, which states,

> *"Mission Hospital is positioned financially to fund the project cost of $1,237,236 through operations and/or accumulated cash reserves. Funds are available for this project, in addition to several other projects which have been approved or are under review by the Agency as reflected in Mission's 2010 Audited Financial Statements, which are included as part of this Application."*

The applicant does not adequately demonstrate the availability of sufficient funds for the capital cost of the project given the developer appears to be incurring 60% of the cost to develop the new institutional health service. Furthermore, the applicant does not adequately demonstrate the availability of sufficient funds for start-up costs likely to be incurred prior to serving patients at the new campus.

In the Pro Forma Section, pages 121 and 125, the applicant provides a statement of revenues and expenses (Form C) for GI endoscopy services at Mission Hospital and Mission GI South. On the statement of revenues and expenses for Mission Hospital (page 121), the applicant projects revenues will exceed operating costs in the first three years of the project. The project years are shown as fiscal years (October 1 – September 30) when, in fact, the applicant's projected utilization is based on calendar years (January 1 – December 31). In Section III.1(b), page 45, the applicant states, *"Calendar year 2010 Trendstar data is the most current and reasonable data to use as a base to project future GI endoscopy utilization. It is also consistent with the project years, which are calendar year-based."* [Also see Section III.1(b), page 50 and Section IV, page 76]. Interestingly, the projected number of cases shown on Form C, which are based on fiscal years, through Project Year 3 are the same as number of cases shown on page 50, which are based on calendar years. It is unusual that the number of cases performed in any given fiscal year would exactly match the number of cases performed in any given calendar year. Thus, the applicant's pro forma projections for GI endoscopy services at Mission Hospital are inconsistent with the methodology in Section III.1(b) and are, therefore, unreliable.

On the statement of revenues and expenses for Mission GI South (page 125), the applicant projects that revenues will exceed operating costs in the first three years of the project. Again, the project years are shown as fiscal years (October 1 – September 30) when, in fact, the applicant's projected utilization is based on calendar years (January 1 – December 31). [See Section IV, page 76 and various tables in Exhibit 16]. Additionally, the projected number of cases for the first three years of the proposed project is inconsistent with the projected number of cases in the applicant's methodology. The inconsistencies are illustrated below:

	Projected # of Procedures	
	Pro Forma (Form C)	Section IV (Page 76)
Project Year 1	1,540*	1,455
Project Year 2	1,557*	1,471
Project Year 3	1,575*	1,487

*Calculated by the Project Analyst. In the Pro Forma Section, the applicant provides the projected number of cases for each Project Year. In Section III.1(b), page 55, the applicant states the ratio of cases to procedures is 1.3. The Project Analyst multiplied the projected number of cases by 1.3 to determine the projected number of procedures for each Project Year. Project Year 1: 1,158 cases x 1.3 = 1,540 cases; Project Year 2: 1,171 x 1.3 cases = 1,557 cases; Project Year 3: 1,184 x 1.3 = 1,575 cases.

As shown in the table above, the projected number of cases in the pro formas is greater than the number of cases the applicant projects to perform it its utilization projections, as provided in Sections III and IV. Thus, the applicant's pro formas for Mission GI South are overstated. Projected revenues for GI endoscopy services at Mission GI South, which are based on projected utilization, are inconsistent with the assumptions and methodology in Section III.1(b) and the projected utilization in Section IV, and are, therefore, unreliable.

Additionally, on the applicant's statement of revenues and expenses (Form C), page 121, for GI endoscopy services at Mission Hospital and Mission GI South, salary expenses for clinical and other personnel are not in line with the salary expenses provided by the applicant in Section VII. In Project Year 3, salary expenses for GI endoscopy services at Mission Hospital and Mission GI South (combined), as provided on Form C, are shown in the table below:

Total Mission GI Endoscopy
Salary Expenses
Project Year 3
(10/1/14 – 9/30/15)

Personnel	Salary Expense
Clinical	$10,949,703
Other	$7,450,692
Total	**$18,400,395**

*Source: Form C, page 121.

However, salary expenses for GI endoscopy services at Mission Hospital and Mission GI South (combined) in Project Year 3, as provided in Section VII.2, page 93, are shown in the table below:

Total Mission GI Endoscopy
Salary Expenses
Project Year 3
(1/1/14 – 12/31/14)

Personnel	Annual Salary (A)	Full-Time Equivalents (FTEs) (B)	Salary Expense (A x B = C)
Registered Nurse	$62,519	17	$1,062,823
Unit Secretary	$31,917	3	$95,751
Endoscopy Tech	$35,169	3	$105,507
RN – Supervisor	$120,748	2	$241,496
Total			**$1,505,577**

*Source: Section VII.2, page 93.

As shown in the two proceeding tables, aside from the inconsistency of the project years, the applicant's salary expenses in the third year of the project differ significantly. Salary expenses on Form C are more than 12 times greater than that provided in Section VII of the application. The applicant does not explain why salary expenses differ so greatly in the assumptions provided in the Pro forma Section. Assuming the salary expenses provided in Section VII are accurate, the salary expenses in Form C are grossly overestimated. This, however, does not reflect negatively on the financial feasibility of the proposed project. However, the Project Analyst could not determine the source of the discrepancy, and the discrepancy is large enough to raise questions as to the reliability of the pro formas in general.

In summary, the applicant does not adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project and does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. Therefore, the application is not conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

Mission Hospital operates six licensed GI endoscopy rooms on its main campus in Asheville and proposes to relocate one of its existing GI endoscopy rooms to a new medical office building in Fletcher. The relocated GI endoscopy room will continue to be licensed as a part of the hospital. However, the applicant did not adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities. The applicant identified nine zip codes in Buncombe and Henderson counties as the primary service area for Mission GI South. In Section III.1(a), page 58, the applicant projects to perform 1,455 procedures at Mission GI South in Project Year 1, 1,471 procedures in Project Year 2, and 1,487 procedures in Project Year

3. The applicant assumes a 10% in-migration rate from counties outside of Buncombe and Henderson counties. The applicant's in-migration assumption is based on the fact that Mission Hospital's historical patient origin consists of 34% in-migration rate from counties other than Buncombe and Henderson counties. However, Mission Hospital is a tertiary regional referral hospital and draws patients from a wide geographic area for a trauma and specialty care. Based on Mission Hospital's current patient origin for inpatient and outpatient GI endoscopy from counties other than Buncombe and Henderson counties [as reported on its 2011 License Renewal Application (LRA)], the Project Analyst estimates that a 7.7% in-migration is more reasonable. [See Criterion (3) for additional discussion.] Thus, the applicant's projected utilization for Mission GI South is overstated. Furthermore, the patient origin information reported on the LRA includes both inpatient and outpatient endoscopy procedures, but only outpatient procedures will be performed at the Mission GI South campus. As such, without making an adjustment for inpatient GI endoscopy procedures, even the Project Analyst's estimate of 7.7% in-migration is overstated.

Additionally, the applicant proposes to locate the proposed Mission GI South on the Buncombe/Henderson County line (literally). From FFY 2008 to FFY 2010, Buncombe County experienced almost no growth in the number of GI endoscopy procedures performed, increasing by just 0.5% from FFY 2008 to FFY 2010. In contrast, Henderson County has experienced a decline in the number of GI endoscopy procedures, decreasing by 10.9% over the same time period. Additionally, the six GI endoscopy rooms in Henderson County are in relative close proximity to the proposed Mission GI South campus—Park Ridge Hospital is approximately 5.15 miles; Carolina Mountain Gastroenterology Endoscopy Center is approximately 11.70 miles; and Margaret R. Pardee Memorial Hospital is approximately 11.80 miles. As can be seen in the previous table, Park Ridge Hospital (the facility in closest proximity to the proposed Mission GI South campus) performed the fewest number of GI endoscopy cases and procedures of the three Henderson County GI endoscopy providers. Park Ridge Hospital performed just 676 procedures per room[2] in FFY 2010—well below the threshold in The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities (10A NCAC 14C .3900) that requires a licensed GI endoscopy room to perform a minimum of 1,500 procedures per room. Given the decline in GI endoscopy utilization in Henderson County, with six GI endoscopy rooms in operation, there is sufficient GI endoscopy capacity in the Mission GI South service area already. Thus, relocating an additional GI endoscopy room to the Buncombe/Henderson County line would result in an unnecessary duplication of existing GI endoscopy services.

In summary, the applicant does not adequately demonstrate that the proposed Mission GI South would not unnecessarily duplicate existing and approved GI endoscopy facilities. Therefore, the application is nonconforming with the criterion.

[2] In the 2011 and 2012 (Proposed) State Medical Facilities Plans (FFYs 2009 and 2010, respectively), Park Ridge is reported as performing 0 procedures. The CON Section assumes Park Ridge performed at least one procedure per case.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The following table illustrates the current and projected staffing for GI endoscopy services at Mission Hospital and the proposed Mission GI South campus, as reported by the applicant in Section VII, pages 93-94.

Employee Category	# of Full-Time Equivalents (FTEs)		
	Mission Hospital (Current) (A)	Mission Hospital & Mission GI South Combined (Project Year 3) (B)	Mission GI South Only (Project Year 3) (C)
Registered Nurse	15	17	3
Unit Secretary	2	3	1
Endoscopy Tech	1	3	2
RN Supervisor	2	2	n/a
Applicant's Total	**21**	**28**	**6**
*Actual Total**	*20*	*25*	*6*

*Calculated by the Project Analyst.
**Source: Sections VII.1 and VII.2.

As can be seen in the table above, there are some discrepancies in the projected staffing data as reported by the applicant. First, the applicant incorrectly added the number of existing full-time equivalents (FTEs) at Mission Hospital (Column A) and the projected number of FTEs for both the Mission Hospital campus and the Mission GI South campus combined in Project Year 3 (Column B). Additionally, while the applicant's table in Section VII.2, page 94, shows a total of six FTEs at the Mission GI South campus, the narrative in Section VII.3, page 94, states that there will be seven new FTEs on the Mission GI South campus after completion of the proposed project.

In Section VII.6(b), page 96, the applicant provides the projected staffing for Mission Hospital and Mission GI South by functional area in Project Year 3, shown in the table below:

Functional Area	Type	# of FTE Positions
Administration	• RN Manager • RN Supervisor	1.00 1.00 **2.00**
Registration	• Unit Secretary	**3.00**
Pre-Procedure	• RNs • Endoscopy Technician	5.00 0.50 **5.50**
Post-Procedure	• RNs • Endoscopy Technician	5.00 0.50 **5.50**
GI Endoscopy Room	• RNs • Endoscopy Technician	8.00 4.00 **12.00**
Total Staffing		**28.00**

As shown in the table above, the applicant projects a total of 28 FTEs on the Mission Hospital campus and the Mission GI South campus (combined) in Project Year 3. While the information in Sections VII.1 and VII.2 is inconsistent, the information provided with regard to the number of FTEs by functional area show that the applicant's staff projections are reasonable.

Exhibit 10 contains letters from the Chief Medical Officer and Senior Vice President of Medical Affairs, the Chief of Staff, and the Interim Vice President of Surgical Services at Mission Hospital, expressing their support for the proposed project. The relocated GI endoscopy room will continue to remain on the Mission Hospital license as one of its total complement of GI endoscopy rooms.

The applicant adequately demonstrates the availability of sufficient manpower and management personnel to provide the proposed GI endoscopy services. Therefore, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

As a provider of trauma and tertiary services, Mission Hospital already provides pathology services and other necessary ancillary support services. Exhibit 20 contains a list of facilities in the region with which Mission Hospital has existing transfer

agreements. A transfer agreement between the Mission GI South campus and Mission Hospital is not needed because the relocated GI endoscopy room on the Mission GI South campus will continue to be licensed as part of Mission Hospital. Exhibit 7 contains letters from the Vice President of Ambulatory and Ancillary Services and the Vice President of Support Services at Mission Hospital stating that the necessary ancillary and support services will be provided. Exhibit 22 contains letters from physicians at Asheville Gastroenterology Associates, P.A. and other physicians and clinical/administrative staff at Mission Hospital stating their support for the proposed project. Consequently, the applicant adequately demonstrated that all necessary ancillary and support services will be available and that the service will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv)would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NC

The applicant proposes to relocate one licensed GI endoscopy room from the main campus of Mission Hospital in Asheville to a new medical office building (MOB) in Fletcher. In Section XI.2, pages 110-111, the applicant states that the land is already owned by Mission Hospital but the MOB will be developed by a third party developer. The applicant states that Mission Hospital will lease space in the MOB for the proposed project. In Section XI.5, the applicant states the project will involve 3,700 square feet of interior construction. In Section XI.6(b), page 115, the applicant estimates construction costs of $166.93 per square foot. In Section XI.8, pages 115-116, the applicant describes the methods to be used to maintain efficient energy operations.

Exhibit 29 contains a letter from a certified architect with a cost estimate for the proposed project. The architect breaks down the cost estimate as follows:

Anticipated site improvement cost	*n/a*	
Anticipated upfit cost ($100/sf)	*$370,000*	
Less Landlord tenant improvement allowance ($25/sf)	*($92,500)*	
Interior upfit subtotal		*$277,500*
Anticipated prorate share of site, shell & core MOB cost (4.28%)	*$850,387*	
Less 60% Ownership adjustment – Mission 40% MOB ownership	*($510,232)*	
Associated building cost subtotal		*$340,155*
Total anticipated cost above		*$617,655*

**Source: Exhibit 29.*

The architect's cost estimate indicates there is a 60/40 ownership "adjustment" between the developer and Mission Hospital. However, the applicant does not provide enough information regarding the basis for determining that there will be a 60/40 ownership "adjustment" between the developer and Mission Hospital. Furthermore, it appears the developer should have been identified as a co-applicant in the application because the applicant does not adequately demonstrate that the developer will not be incurring an obligation for a capital expenditure which is a new institutional health service (i.e., developing space for a relocated GI endoscopy room in a licensed health service facility). Mission Hospital is the only applicant identified in the application. The applicant did not adequately demonstrate that the cost of construction represents the most reasonable alternative. Therefore, the application is nonconforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The following table illustrates the current payor mix for the GI endoscopy department at Mission Hospital, as reported by the applicant in Section VI.13, page 91.

ENDOSCOPY DEPARTMENT *LAST FULL FISCAL YEAR (10/1/09 – 9/30/10)* *CURRENT CASES AS PERCENT OF TOTAL CASES*	
Self Pay / Indigent	*5.24%*
Medicare / Medicare Managed Care	*50.42%*
Medicaid	*13.15%*
Commercial Insurance	*1.31%*
Managed Care	*27.69%*
*Other (Specify)**	*2.19%*
TOTAL	*100.00%*

**Other includes Workers Comp & State Employee Benefit Health Plan*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2009 and CY 2005, respectively. The data in the table was obtained July 27, 2011. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2005 (Estimate by Cecil G. Sheps Center)**
County			
Buncombe	16%	7%	16.7%
Henderson	13%	5%	17.6%
Statewide	16%	7%	17.2%

*Source: DMA Website: http://www.ncdhhs.gov/dma/pub/index.htm

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the endoscopy department at Mission Hospital.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The

DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of July 27, 2011, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.2, page 85, the applicant states, *"Mission provides and will continue to provide acute care inpatient and outpatient services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay."* In Section VI.10(a), page 90, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against Mission Hospital in the last five years. The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

The following table illustrates the projected payor mix for Mission Hospital's GI endoscopy department during the second operating year of the proposed project, as reported by the applicant in Section VI.14, page 92.

ENDOSCOPY DEPARTMENT (1/1/14 – 12/31/14) PROJECTED CASES AS PERCENT OF TOTAL CASES	
Self Pay / Indigent	*5.24%*
Medicare / Medicare Managed Care	*50.42%*
Medicaid	*13.15%*
Commercial Insurance	*1.31%*
Managed Care	*27.69%*
*Other (Specify)**	*2.19%*
TOTAL	*100.00%*

**Other includes Workers Comp & State Employee Benefit Health Plan*

In Section VI.6, pages 87-88, the applicant states,

> *"It is the policy of all Mission Hospital facilities to provide care to all who seek it, regardless of their ability to pay. Mission has policies and procedures in place to identify those patients who require financial assistance and to ensure that these patients receive the aid they need to access health services."*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services and the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9(a), page 89, the applicant states, *"GI endoscopy patients are referred to Mission from hospitals and physician practices in the region. Patients presenting in the Emergency Department are predominantly self-referral and will be admitted to acute care beds when clinically appropriate. It is also anticipated that the local physicians will directly refer patients for GI endoscopy services as necessary."* The information provided is reasonable and credible and supports a finding of conformity with this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1(a), the applicant describes the institutions with which Mission Hospital participates in professional training programs. Additionally, Exhibit 19 includes an affiliation agreement with the Mountain Area Health Education Center Family Practice Residency. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant did not adequately demonstrate that the proposal would have a positive impact on cost-effectiveness because the applicant did not adequately demonstrate that the proposal is cost-effective [see Criteria (3), (4), (5), and (6) for additional discussion]. Therefore, the application is nonconforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Mission Hospital is accredited by The Joint Commission. In Section II.7, page 12, the applicant states, *"The proposed project will meet all state and federal regulatory licensure requirements, including OSHA, Division of Health Services Regulation ("DHSR") licensure, and all health facility requirements of the Buncombe County Department of Health."* According to the records in the Acute Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at Mission Hospital within the 18 months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant does not propose to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a new GI endoscopy room in an existing licensed health service facility (Mission Hospital would remain licensed for no more than six GI endoscopy rooms). Thus, the Criteria and Standards for Gastroenterology Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900, are not applicable to this review.

mapquest

Trip to:
10628 Park Rd
Charlotte, NC 28210-8407
9.01 miles
21 minutes

Notes

Distance from CR-Main to CMC-Pineville
Exhibit E

	1100 Blythe Blvd Charlotte, NC 28203-5814	**Miles Per Section**	**Miles Driven**
	1. Start out going **south** on **Blythe Blvd.**	**Go 0.05 Mi**	0.05 mi
	2. Take the 1st **right.** *If you reach the end of Blythe Blvd you've gone a little too far*	**Go 0.2 Mi**	0.2 mi
	3. Turn **left** onto **Garden Ter.** *If you are on Loop Rd and reach Scott Ave you've gone about 0.1 miles too far*	**Go 0.2 Mi**	0.4 mi
	4. Turn **right** onto **East Blvd.** *Caribou Coffee is on the right*	**Go 0.3 Mi**	0.7 mi
	5. Turn **left** onto **Kenilworth Ave.** *Kenilworth Ave is just past Scott Ave* *Berrybrook Farm Natural Foods is on the corner* *If you reach Charlotte Dr you've gone a little too far*	**Go 0.6 Mi**	1.2 mi
	6. **Kenilworth Ave** becomes **Park Rd.**	**Go 7.0 Mi**	8.3 mi
	7. Turn **right** to stay on **Park Rd.** *Park Rd is 0.1 miles past Park Crossing Dr* *If you are on Johnston Rd and reach Oakbrook Dr you've gone about 0.1 miles too far*	**Go 0.8 Mi**	9.0 mi
	8. **10628 PARK RD** is on the **right.** *Your destination is 0.2 miles past Willow Ridge Rd* *If you reach Pineville-Matthews Rd you've gone about 0.1 miles too far*		9.0 mi
	10628 Park Rd Charlotte, NC 28210-8407	**9.0 mi**	**9.0 mi**

Total Travel Estimate: **9.01 miles - about 21 minutes**