COMMENTS BY PARK RIDGE HEALTH ON THE CON APPLICATION FILED BY MISSION HOSPITAL, INC. TO RELOCATE AN ENDOSCOPY ROOM TO FLETCHER, NC
PROJECT I.D. NO. B-008638-11

Park Ridge Health ("Park Ridge") submits these comments on the CON application filed on March 15, 2011 by Mission Hospital, Inc. ("Mission") to relocate one GI endoscopy room from Mission's Asheville campus to a new medical office building ("MOB") located at 2651 Hendersonville Road in Fletcher, North Carolina. This location is on the border of Buncombe and Henderson Counties. The project is proposed to be called "Mission GI South."

According to the property deeds submitted in Exhibit 28 of the application, some of the and on which the MOB will sit is physically located in Henderson County, as two of the three deeds included in Exhibit 28 were recorded in Henderson County. According to the site plan in Exhibit 29, the Buncombe/Henderson county line actually goes right through the proposed MOB, with part of the building located in Buncombe County and part of the building, and most of the parking for the building, located in Henderson County. Although the drawings submitted with the application are not especially clear, it appears that the county line either goes through, or is inches away from, the endoscopy room itself. *See* Exhibits 6 and 29 to the application.

For the reasons stated below, the CON application should be denied because the project fails to meet several of the mandatory criteria in the CON Law. Failure to meet any one criterion in the CON Law means the project must be disapproved. *See Presbyterian Orthopaedic Hospital v. NCDHR,* 122 N.C. App. 529, 534, 470 S.E.2d 831, 834 (1996).

As the Agency reviews this application, it is important to keep in mind that an applicant proposing to relocate an existing endoscopy room must demonstrate conformity with all the review criteria, just as an applicant proposing a new endoscopy room must also demonstrate conformity with all the review criteria. A relocation application must be reviewed as rigorously as any other CON application; there are no "shortcuts" in CON review just because the applicant proposes to relocate an existing asset.

The fact that an endoscopy room is already in existence does not mean that the population proposed to be served needs the endoscopy room in a different location. The Agency made this point clear in the April 6, 2011 findings issued to Wake Forest Ambulatory Ventures, LLC, Project I.D. No. G-8608-10, a copy of which is attached to these comments as Exhibit A. There, the applicant proposed to relocate three existing underutilized operating rooms from Winston-Salem to Clemmons. The Agency disapproved the project because the applicant failed to demonstrate the need for the operating rooms in Clemmons. The failure to demonstrate need under Criterion 3 in turn caused the Agency to find the project non-conforming with Criteria 4, 5, 6, and 18a. The same results should apply here.

I. THE APPLICATION FAILS TO SATISFY CRITERION 3.

Criterion 3 of the CON Law requires the applicant to document the population proposed to be served by the project and the need that population has for the services proposed. The first ten pages of the need section of the application are spent discussing the prevalence of gastrointestinal disorders, the importance of early detection of colorectal cancer, colon cancer screening rates and outpatient colonoscopy procedure rates. *See* application, pages 21-30. By page 31, however, the application reveals a fundamental problem with the Mission GI South project: Mission's outpatient endoscopy volumes are declining. *See* application, page 31. Outpatient endoscopy is the service proposed in the Mission GI South application. *See* page 31 of the application, showing that between CY 2008 and CY 2010, Mission's outpatient endoscopy volumes declined by 267 cases and 194 procedures, respectively. Applying the 1,500 procedures per room standard in 10A NCAC 14C.3903, Mission's volume declines show that Mission barely has enough volume to support the six endoscopy rooms it now has. *See, e.g.,* CY 2010 volumes on page 31 (8,661/1,500 =5.77 rooms). According to Tables 2 and 3, Exhibit 16 in the application, the compound annual growth rate (CAGR) for CY08-CY10 for all endoscopy procedures at Mission is *negative* 0.2%.

The endoscopy use rate has also declined sharply in Buncombe County. *See* application, page 34 and Table 9, Exhibit 16, showing that in FY 2007, the endoscopy use rate in Buncombe County was 51.8. In FY 2010, it declined to 49.1. In Henderson County, the use rate increased from 55.7 to 58.2, but even when the two counties are combined, the combined 2010 use rate is still below the combined 2007 use rate.

Mission "reasonably believes" the economic downturn is responsible for the decline in the utilization of outpatient endoscopy. *See* application, page 34. While the economy may have played a role in Mission's volume declines, it seems unlikely that the economy bears all the responsibility for Mission's volume declines. That is because Mission's competitor, The Endoscopy Center, which operates five outpatient only endoscopy rooms less than a mile from Mission, has maintained its high procedure volumes of more than 14,000 procedures annually during the three year period FY 2008 through FY 2010. *See* application, page 32. While The Endoscopy Center experienced a slight drop in volume in FY 2010 when compared to FY 2009, its FY 2010 volume is still significantly higher than its FY 2008 volume. And The Endoscopy Center's FY 2009 volume, which was higher than both FY 2007 and FY 2010, occurred at a time when the economic downturn was at its worst. The Endoscopy Center operates in the same economy in which Mission operates, so if the economy caused a decline in Mission's volumes, one would reasonably expect to see The Endoscopy Center's volume also decline. Yet the Endoscopy Center experienced robust volumes.

In fact, Mission relies on The Endoscopy Center's robust volumes to support the proposition that Buncombe County needs an additional 4.6 endoscopy rooms. *See* application, page 32. But The Endoscopy Center is not the applicant here, so Mission cannot leverage The Endoscopy Center's robust volumes to prop up its declining volumes.

In the Wake Forest Ambulatory Ventures, LLC findings, the Agency cited the decline in inpatient surgery at North Carolina Baptist Hospital, and the applicant's failure to explain why those volumes were going down, as a reason to deny the application under Criterion 3. The decline in volume casts doubt on future growth. *See* Exhibit A, pages 12, 13 and 24. Likewise, in the 2010 Wake County MRI review, the Agency cited Wake Radiology's declining MRI volumes as a reason to disapprove Wake Radiology's CON application for an MRI scanner in Garner. *See* Exhibit B, page 34. The same concerns exist here.

Mission states that the project will result in "improved" access. *See* page 32 of the application. Yet Mission does not provide any evidence to support the notion that access to outpatient endoscopy in the Asheville area needs to be "improved." In fact, in the nine zip code service area defined by the applicant, there are already six endoscopy rooms: Carolina Mountain Endoscopy Center (2 rooms in zip code 28791), Pardee Hospital (3 rooms in zip code 28791) and Park Ridge (1 room in zip code 28792).

On page 12 of the application, Mission states that "[c]urrently, 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."

Visiting the Mission campus is not nearly as challenging as this description suggests. Central Asheville is not plagued with traffic. Mission's campus is not mountainous. According to its website, Mission offers free parking and shuttle services, and valet parking on the Memorial campus for $4.00. *See* http://www.missionhospitals.org/body.cfm?id=2133 and http://www.missionhospitals.org/ShuttleService.

There are no letters from any patient indicating any challenges accessing Mission's endoscopy services. None of the physician letters included in Exhibit 10 of the application indicates that any patient has complained about access. There is nothing in the application to substantiate the proposition that terrain, parking decks and the number of buildings on the Mission campus has anything to do with Mission's declining outpatient endoscopy volumes, or that this trend will be reversed if Mission relocates an endoscopy room to the Buncombe/Henderson border.

Moreover, several other facilities in the area provide convenient access to outpatient endoscopy for residents of Buncombe and Henderson Counties. The Endoscopy Center, located at 191 Biltmore Avenue in Asheville, less than a mile from Mission, has five endoscopy rooms. The Endoscopy Center offers free parking, does not have any parking decks and is focused solely on outpatient endoscopy. Both Mission and The Endoscopy Center are in zip code 28801, which is adjacent to two of the zip codes in the service area: 28806 and 28803. Mission does not explain why it would be reasonable to expect patients in zip codes 28806 and 28803 to drive to the Buncombe/Henderson border when they can easily get to Mission or The Endoscopy Center.

There are also three other providers of outpatient endoscopy in nearby Henderson County, which includes two of the zip codes in the proposed service area for Mission GI

South: Carolina Mountain Endoscopy Center (2 rooms), Pardee Hospital (3 rooms) and Park Ridge (1 room). Each of these facilities is easy-to-navigate and offers free parking. Park Ridge has recently spent $26,000,000 to build a 20-bed outpatient surgery center and created state of the art operating rooms where it provides high-quality endoscopy services to residents of Buncombe and Henderson Counties. Mission does not explain why it would be reasonable to expect patients living in zip codes 28791 and 28792 to bypass these existing providers and go to Mission GI South.

Access to outpatient endoscopy is clearly *not* a problem in the Buncombe/Henderson area.

The applicant's definition of the service area for the project includes nine zip codes that straddle Henderson and Buncombe Counties; this zip code region is inconsistent with the service area definition contained in 10A NCAC 14C .3901(6) that is based specifically on county boundaries. Also, the 2011 State Medical Facilities Plan shows that counties are used to describe the geographical service areas for endoscopy rooms.

It is unreasonable for Mission to project that its patient origin percentages will remain unchanged with the proposed relocation of one GI endoscopy room to a medical office building 10 miles to the south of the current facility. *See* application, pages 70 and 71. This is because Mission's self-defined service area for this one GI endoscopy procedure room is comprised of nine zip codes which is a different service area Mission's Hospitals service area definition that has been comprised of 13 counties. Since this endoscopy room is moving to the Buncombe/Henderson border, one can reasonably expect that the facility will attempt to attract more Henderson County patients.

Mission states that the physicians associated with The Endoscopy Center support the Mission GI South project. *See* page 32 of the application. In Exhibit 10, there is a letter of from four of the eighteen gastroenterologists at Asheville Gastroenterology Associates, P.A. ("AGA"). AGA owns The Endoscopy Center. The letter in Exhibit 10 is a self-described "expression of interest" by the four undersigned physicians. The physicians do not, however, commit to perform any number of procedures at Mission GI South. Therefore, the Agency cannot determine that the "interest" of these four physicians will translate into procedure volume at Mission GI South. Further, as owners of The Endoscopy Center (for which they receive both facility fee income and professional fee income), one wonders how serious the "interest" of these physicians in using Mission GI South really is, as Mission GI South would take facility fee revenue away from The Endoscopy Center. In the findings for Wake Forest Ambulatory Ventures, LLC, the Agency noted that the applicant failed to provide letters of support from any community physicians indicating the number of surgical cases they expect to perform at the applicant's proposed facility. *See* Exhibit A, page 25. One also wonders if these physicians may have been promised something in return for their support, such as a joint venture opportunity, which is not disclosed in the application.[1]

[1]Exhibit 34, which is the lease term sheet, indicates that the landlord is a "real estate LLC" that will be named at a later date. It is reasonable to ask whether the landlord is AGA.

The physicians' "expression of interest" states that "the proposed relocation will expand access and choice for residents of the rapidly growing population of southern Buncombe County who require outpatient GI endoscopy services. The Mission GI South Location in southern Buncombe County is desirable to health care consumers and physicians in our community because it will provide high quality patient care in a location that is convenient and easily accessible." *See* Exhibit 10 to the application.

There are several noteworthy points about this letter. First, while the letter talks about "expand[ed] access," there is nothing in the letter or in the application otherwise to show that access is a problem at all, and that access to outpatient endoscopy needs to be "expanded" through Mission GI South. As previously noted, there are already six endoscopy rooms in the service area proposed by the applicant, and eleven more endoscopy rooms in an adjacent zip code (28801). Second, while the letter states that the location is "desirable" to health care consumers, no patient filed a letter of support for this project. Third, the letter states that the Mission GI South project will "expand choice" for residents, but the letter fails to mention that there are three other providers in the southern Buncombe/Henderson County area that already offer this choice in convenient, easily-accessible settings, *in addition to AGA's own five-room endoscopy center.* There is no indication in the application that any of these providers (The Endoscopy Center, Carolina Mountain Endoscopy Center, Pardee or Park Ridge) is unable to accommodate the needs of patients. Patients already have abundant access to, and significant choice of, endoscopy providers in the Buncombe/Henderson area, so Mission GI South does not bring anything new or needed to the table. Fourth, the according to the deeds and drawings submitted with the application, part of the property on which Mission GI South will be located is actually in Henderson County, not Buncombe County, so it is incorrect to imply, as Mission does, that this project is wholly inside Buncombe County. Mission GI South is strategically positioned so that Mission can attempt to attract more Henderson County patients. *See* Exhibits 6, 28 and 29 to the application.

Given its own declining outpatient volumes, Mission itself has capacity to accommodate more endoscopy patients. Thus, the situation here is very different from the findings cited on page 19 of the Mission application, Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC, in which the Agency noted waiting times for appointments ranging from six to nine weeks. *See* Exhibit C, page 4.

Mission then proceeds to discuss population growth in Buncombe and surrounding counties, noting the fact that the Asheville area is a popular place for retirees. *See* application, page 37. This is not new information; Asheville has been popular with retirees for many years. The articles that Mission cites from *Modern Maturity* and *Money* magazines date from the year 2000. Yet, despite the influx of retirees, Mission's outpatient endoscopy volume is not growing; in fact, it is declining. *See* application, page 32. *See also* Exhibit D (references to the dates on which these articles were published).

On pages 38-43 of the application, Mission provides extensive discussion about the growth and development in Buncombe County and in Fletcher, specifically. This information does not demonstrate that Mission needs to relocate an endoscopy room to the Buncombe/Henderson border. Mission does not make any connection between new business

coming into the area, the number of endoscopy cases that may result from the employees working in these businesses and whether Mission GI South would capture any particular number of any endoscopy cases that comes as a result of this growth.

The Town of Fletcher, where Mission proposes to establish Mission GI South, is physically located in Henderson County. Additionally, the deed to the property on which MI GI South will be located is actually in Henderson County. *See* Exhibit 28 to the application, reflecting that the site is located in Henderson County and the deed was recorded in Henderson County. There are already three existing providers of outpatient endoscopy in Henderson County: Carolina Mountain Endoscopy Center, Pardee or Park Ridge. Park Ridge is just a few miles from Mission's proposed site. *See* Mapquest map at Exhibit E. Carolina Mountain Endoscopy is approximately 10 miles from Mission's proposed site. *See* Exhibit F. Pardee is also about 10 miles from Mission's proposed site. *See* Exhibit G. Outpatient endoscopy is a non-emergent, scheduled outpatient procedure. There is nothing about Henderson County geography or traffic conditions that would make it unreasonably difficult for patients to get to these three locations. Likewise, Mission and The Endoscopy Center are about 10 miles from the proposed Mission GI South. *See* Exhibits H and I. There is no information in the application to substantiate that it is unreasonably difficult for patients to travel to Asheville for endoscopy.

On page 43 of the application, Mission optimistically states that "[w]hen the economy improves and national health reform is implemented, the demand for GI endoscopy services will grow once again, particularly with the impact of the growing 65+ population." The problem with this assertion is that no one knows when the economy will improve. The future of health care reform is also unknown. Further, Mission does not even attempt to quantify how improvements in the economy or implementation of health care reform will lead to increased utilization of *Mission's* outpatient endoscopy services. The CON process requires documentation and demonstration of need, not speculation about circumstances that are well beyond the applicant's control.

Mission next presents a 10-step methodology to demonstrate the need for this project. Step 1 of the methodology compares Mission's internal data (Trendstar) to the data it reports on its annual Hospital License Renewal application. As the first chart on page 45 shows, there is a significant variation in the number of cases and procedures reported in Trendstar versus the number of cases and procedures reported in the annual Hospital License Renewal Application. The internal data is not "very consistent" with the data Mission reports on its Hospital License Renewal application, as Mission claims. Mission states that it elected to use the Trendstar data for its projections. The Trendstar data, as depicted in the second table on page 45 of the application, clearly shows that Mission's outpatient endoscopy volume has declined significantly from CY 2008 to CY 2010, and that its combined inpatient and outpatient endoscopy volume has also declined from CY 2008 to CY 2010.

In Step 2 of the methodology, Mission develops its growth rate of *negative* 0.2%. *See* application, page 48. While Mission proclaims that its growth rate is "conservative," the Agency must ask why, in the face of declining volumes and a negative growth rate, it should award a CON to Mission to spend more than a million dollars to move an endoscopy room to

an area that is already well-served by endoscopy providers. CON is intended to promote cost control, not wastefulness or unnecessary duplication of services. *See* N.C. Gen. Stat. § 131E-175(4).

As Step 3 of the methodology and the chart on page 49 of the application shows, Mission projects to perform *fewer* endoscopy procedures and cases in 2015 (Project Year 3) than it performed in 2010. CONs are to be awarded only where there is a demonstrated need for a project. Declining volumes and a negative growth rate are certainly not indicative of a need for a project; rather, they indicate exactly the opposite, *i.e.,* the project is *not* needed. The declining volumes and negative growth rate also undermine the preceding pages of the application where Mission speaks of the growth in the Asheville area and its optimism that once the economy improves and health care reform is implemented, more people will have endoscopies. As previously noted, the application does not offer any reasonable explanation that the endoscopy room will be better utilized if the endoscopy room is moved to Fletcher. In fact, the application shows just the opposite – Mission projects that its volumes will go down if the room is moved to Fletcher.

In Step 4 of the methodology, Mission tries to minimize the volume decline by calling it "a very slight reduction." *See* application, page 50. A reduction is a reduction, and a reduction does not indicate a need for a CON. Moreover, this reduction is not "very slight." The volume is going down every year from CY 2011 to CY 2015. Measured cumulatively from CY 2010 to CY 2015, Mission's procedure volume is going down by 246 procedures or 189 cases. The question is not whether Mission continues to show a need for 6 endoscopy rooms, as Mission states on page 50 of the application – the question is whether Mission has shown a need to relocate a room to Fletcher. The answer to that question is no.

In Step 5 of the methodology, Mission again discusses the use rate for endoscopy in Buncombe and Henderson Counties. As previously noted, the use rate in Buncombe County, which is the county from which Mission GI South projects to derive a substantial majority (56.8%) of its patients, is going down.

In Step 6, 7 and 8 of the methodology, Mission projects the base population for the Mission GI South service area, and the projected number of endoscopy cases and procedures in the service area for the first three project years. These calculations do not help Mission because, as noted in Step 3, Mission's own growth is negative and its volumes are projected to go down.

In Step 9, Mission provides its market share of the total endoscopy cases in Buncombe County for 2007 and 2010. The table on page 55 shows that Mission's market share has decreased significantly (by 6.5 basis points), while the market share for The Endoscopy Center has increased substantially (by 4.8 basis points). Carolina Mountain Endoscopy Center has also experienced a significant market share increase (2.5 basis points).

On page 56 of the application, Mission performs the same exercise for Henderson County, and again, Mission's market share of the endoscopy cases in Henderson County,

which was in the single digits in 2007, has declined (by 1.9 basis points). Carolina Mountain Endoscopy Center experienced a significant market share increase (31.2 basis points).

Using all this data, Mission arrives at Step 10 of the methodology on page 56 of the application. Mission states on page 56 that it "reasonably assumed" that Mission GI South would capture 70% of Mission's FY 2010 county-specific market share in Step 9. Mission does not explain how it selected this percentage. Given that Mission's market share of GI endoscopy cases in Buncombe and Henderson Counties is steadily going down, it does not seem reasonable for Mission to assume that it would steadily capture 70% of its 2010 county-specific market share in all three project years. Rather, the trend line over the past several years has been that the market share is declining. Given that Mission has not provided any information to explain how this trend would be reversed, it is not reasonable to expect a consistent market share going forward.

Mission Hospitals' historical data demonstrates a decline in outpatient utilization due to market share loss to the freestanding ASCs with GI endoscopy rooms. This data shows that more patients are choosing to obtain colonoscopy procedures at freestanding GI endoscopy centers where patient charges are substantially lower as compared to the hospital-based charges. Across North Carolina, licensed freestanding ambulatory surgery centers with GI procedure rooms are being used to perform an increasing percentage of the total GI endoscopy demand.

The total number of endoscopy procedures performed in licensed ambulatory surgical centers in North Carolina increased from 98,588 procedures in the 2005-06 annual period to 270,181 procedures in the most recent 2008-09 annual period.

Reporting Periods	# of Procedure Rooms in Hospitals	# of Procedure Rooms in ASCs	Total # Procedures Performed in ASC plus Hospitals	# of Procedures Performed in ASC	% of Total Procedures Performed in ASC
2005-06	285	119	489,899	98,588	20.12%
2006-07	289	144	551,484	165,337	29.98%
2007-08	286	164	585,024	233,740	39.95%
2008-09	284	169	591,693	270,181	45.66%

Sources: North Carolina State Medical Facilities Plans (2008 to 2011)

Contrary to statewide trends and local market share data, the Mission application fails to project forward the highly probable market share gains for The Endoscopy Center in Buncombe County and Carolina Mountain Gastroenterology Endoscopy Center in Henderson County.

Mission's market share projections are based on the unreasonable assumption that the proposed project will immediately capture and hold 22.7% of the GI endoscopy market share

from the Buncombe zip codes and 5.1% of the market share from the Henderson zip codes. These market share assumptions are unreliable because:

- Mission fails to provide a list of the types of outpatient GI endoscopy procedures by CPT code that the proposed project will be able to accommodate. Without this underlying data, it is impossible to evaluate the reasonableness of the market share assumptions.
- No ramp-up in volume is projected in Year 1 even though it will take considerable time for both patients and physicians to change established referral and practice patterns.
- The application fails to demonstrate the average number of physicians that will utilize the one GI room facility on a daily or weekly basis.
- Mission fails to demonstrate that a single GI endoscopy procedure room located in a medical office building can operate as efficiently as multiple endoscopy procedure rooms in existing facilities.

At the bottom of page 57, Mission provides a chart showing that by PY 3, 1,338 endoscopy procedures will be performed at Mission GI South. This number is well below the planning metric of 1,500 procedures per year per room. In an attempt to salvage this situation, Mission projects 10% inmigration on page 58 of the application, which generates an additional 149 procedures by PY 3. Mission does not explain how it arrived at 10% inmigration. Mission says that this 10% will come from "other Buncombe and Henderson zip codes" and "other counties." *See* application, page 58.

There are several problems with Mission's inmigration assumptions. First, there is a discrepancy in the inmigration percentage, which in turn creates a discrepancy in the number of procedures. On page 58, the inmigration percentage is represented to be 10%. In Exhibit 15, Table 5, it is represented to be 15%. This changes the procedure volumes and also cases further doubt on Mission's representation that the patient origin at Mission GI South will be "the same" as it is at Mission's main campus. *See* application, pages 70 and 71.

The application fails to explain the discrepancies in the projected numbers of in-migration procedures. Page 58 is based on an assumption of 10% in-migration; Exhibit 16, Table 5 is based on approximately 15 percent. Based on these conflicting representations, the utilization projections are inaccurate and unreasonable.

Page 58	PY 1: 2013	PY 2: 2014	PY 3: 2015
Buncombe-Henderson Zip Codes - OP GI Endoscopy Procedures	1,309	1,324	1,338
In-migration (10%)	145	147	149
Total Projected OP GI Endoscopy Procedures	1,455	1,471	1,487
Exhibit 16. Table 5.	2013	2014	2015
Combined Buncombe-Henderson GI Endoscopy Procedures at Mission South	1,309	1,324	1,338
Other In-migration	231	234	236
Total Projected Procedures at Mission South GI Locatior	1,540	1,557	1,574

The utilization projections provided in Section IV, Table IV on page 76 are also inconsistent with the utilization projections provided in Exhibit 16, Table 16 as follows:

Table IV GI Endoscopy	CY 2013	CY 2014	CY 2015
Mission Campus # GI Procedures	7,157	7,125	7,092
Mission South # Outpatient GI Procedures	1,455	1,471	1,487
Total # GI Procedures	8,612	8,596	8,579
Exhibit 16. Table 16.	CY 2013	CY 2014	CY 2015
Mission GI South	1,540	1,557	1,574
Mission Hospital	7,687	7,867	8,052
Total Mission GI Procedures	9,227	9,424	9,626

Based on these conflicting projections the applicant fails to demonstrate that the utilization projections are based on reasonable assumptions.

Second, according to Exhibit 16, Table 12, Mission inpatient and outpatient endoscopy services have attracted patients from a range of counties in Western North Carolina, but Mission does not provide a breakdown of how many of these patients were inpatients or outpatients. Mission does not specifically identify the "other Buncombe and Henderson zip codes" or the "other counties" from which the inmigration would come.

Third, Mission does not provide any information in the application to explain why it would be reasonable to expect patients in "other Buncombe and Henderson zip codes" to go to Mission GI South, given the other options available (*e.g.*, Mission, The Endoscopy Center, Carolina Mountain, Pardee and Park Ridge). In some cases, residents in these "other" zip codes would actually have to drive past an existing provider to get to Mission GI South, and there is no information in the application to explain why a patient in these "other" zip codes would be willing to drive past an existing provider to go to Mission GI South. For example, zip code 28739 is adjacent to the service area, but to get to Mission GI South, a resident of that zip code would have to drive past five endoscopy rooms at Pardee and Carolina Mountain before reaching Mission GI South.

Fourth, Mission's claim that patients from other counties would be likely to travel to the Buncombe/Henderson border for outpatient endoscopy is even less plausible. Mission does not explain, for example, why it would be reasonable to expect a patient from McDowell County to drive an hour to have outpatient endoscopy on the Buncombe/Henderson border, when that patient could just as easily get to McDowell Hospital, Mission or The Endoscopy Center for the same service. Nor does Mission explain why it would be reasonable for a patient in Haywood County, for example, to travel anywhere from 35 minutes to an hour to get an outpatient endoscopy on the Buncombe/Henderson border, when the patient could have the procedure done at Haywood Regional Medical Center, Mission, or The Endoscopy Center. And if patients really are inclined to travel that far, there are already three choices for the service near the Buncombe/Henderson border: Carolina Mountain, Pardee and Park Ridge.

Fifth, the inmigration percentage is further called into question by the fact that outpatient endoscopy is a non-emergent, scheduled procedure. It is not like other services, *e.g.*, emergency department visits, where it is reasonable to expect that some patients who do not live in or near the service area may use the applicant's facility because of a random event, *e.g.*, an accident or the sudden onset of illness.

The unavoidable facts are that Mission's outpatient endoscopy volume is going down and there are numerous other convenient choices in the market for outpatient endoscopy. Just as the applicant in the recent Wake Forest Ambulatory Ventures findings failed to demonstrate the need for the relocation of the operating rooms, Mission has likewise failed to demonstrate the need to relocate an endoscopy room and the project should be disapproved under Criterion 3.

II. THE APPLICATION FAILS TO SATISFY CRITERION 3A.

Criterion 3a of the CON Law specifically applies in relocation projects such as this one. It requires the applicant to demonstrate that the needs of the population presently served will be met, and to explain the effect that reduction in service will have on medically underserved populations. Page 61 of the application asks the applicant to demonstrate

> *d. that the relocation will not have a negative impact on the patients served in terms of any changes in services, costs to the patient, or level of access by medically underserved populations.*

The application is nonconforming to Criterion 3a due to the applicant's failure to evaluate how the project will reduce access to patients from Yancey and Madison Counties (with a combined population of approximately 40,000). 17.8% of Yancey County's residents live below the poverty line, and 19.3% of Madison County's residents live below the poverty line. *See* Exhibit J. Both of these counties are included with Buncombe County in the acute care service area controlled by Mission. As seen in the table on page 73 of the Mission application, neither Yancey nor Madison County has a hospital or a freestanding ambulatory surgical facility with GI endoscopy procedure rooms. The proposed project by Mission shifts one of its six GI endoscopy procedure rooms to be further away from the populations of

Madison and Yancey Counties. This reduction in GI endoscopy capacity in Asheville will certainly have a negative impact access for patients from these counties. In contrast to the populations in southern Buncombe and northern Henderson, patients from Yancey and Madison Counties are geographically isolated and have limited access to GI Endoscopy procedure rooms.

III. THE APPLICATION FAILS TO SATISFY CRITERION 4.

Criterion 4 of the CON Law requires the applicant to demonstrate that it has chosen the least costly or most effective alternative. An applicant that is found non-conforming with Criterion 3 is usually also found non-conforming with Criterion 4. *See* Exhibit A. Since Mission has failed to demonstrate the need for the Mission GI South project under Criterion 3, it should also be found non-conforming under Criterion 4 for failing to demonstrate that its proposal is the least costly or most effective alternative.

IV. THE APPLICATION FAILS TO SATISFY CRITERION 5.

Criterion 5 of the CON Law requires the applicant to demonstrate that the availability and commitment of funds for the project, and that the project will be financially feasible. The Mission application fails both prongs of Criterion 5.

Exhibit 26 to the application is a CFO funding letter dated March 15, 2010 for the addition of nine acute care beds. The amount indicated in the letter is $245,000. The letter is obviously not for the endoscopy project. There is no other letter in the application evidencing the availability and commitment of funds for the endoscopy project. The Agency cannot speculate whether Mission has the funds for the endoscopy project. It is the applicant's responsibility, not the Agency's, to demonstrate the availability and commitment of funds. *See* N.C. Gen. Stat. § 131E-183(a)(5).

In addition, and as discussed above with regard to Criterion 3, projected utilization is unreasonable. Thus, costs and revenues that are based on this projected utilization are also unreliable. *See* Exhibit A.

Capital costs also appear to be understated. In Section XI of the application, page 110, Mission represents that it owns the land upon which the medical office building will be located. *See also* Exhibit 28 to the application. Mission states it will lease the land to the developer of the MOB. *See* application, page 111. Yet no land cost was included in the Section VIII capital cost form. *See* application, page 99. Since Mission is the entity incurring the cost for the land, the land cost needs to be reflected in the capital cost form.

The application does not conform to Criterion 5 because the capital cost projections are unreliable and the operational projections are inaccurate. The project capital cost includes the conceptual cost estimate that is provided in Exhibit 29. This conceptual cost letter is unreliable because:

- The application fails to demonstrate that the Exhibit 29 "conceptual cost estimate" is an acceptable substitute for a certified construction cost estimate.
- The proposed facility plans fail to include areas for endoscopy waiting, registration and reception. Therefore, the omission of these spaces cause the construction cost to be unreliable.
- Exhibit 29 shows that the architect's cost certification includes unsubstantiated deductions for a landlord /tenant improvements allowance. This allowance is unsupported because no landlord legal entity yet exists as seen in lease terms sheet in Exhibit 34.
- The architect letter unreasonably assumes that the project will have a pro rata share of the site, shell & core Medical Office Building ("MOB") of 4.28%. This assumption is unreliable because the remaining 95.72 % of the MOB has not been adequately described in the project application.
- The cost estimate fails to adequately explain the basis for the 60% Ownership adjustment amount of $<510,232>.

Operational projections for the project are unreliable as discussed in the Criterion 3 comments. Consequently, the financial projections for the project are unreasonable because these are based on unreliable volume projections. Mission fails to explain the basis for its projected average charge per GI endoscopy case. The financial statements, worksheet and assumptions fail to include the charge per procedure for the outpatient GI endoscopy procedures that are proposed to be shifted to the proposed project.

Expenses for the proposed project are understated and inaccurate due to the omission of staff positions as described in the Criterion 7 comments regarding anesthesia, business office, reception and registration personnel.

Mission fails to describe any start-up costs associated with the new service location. It is most unreasonable to project no start-up costs because the proposed location will incur new and additional utilities costs, lease expenses and initial inventory costs that are not being incurred at present.

Therefore, the project is non-conforming under Criterion 5. *See also* Exhibit A (Wake Forest Ambulatory Ventures findings).

V. THE APPLICATION FAILS TO SATISFY CRITERION 6.

Criterion 6 of the CON Law requires the applicant to demonstrate that its project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. As discussed above, there are already abundant resources available in Buncombe and Henderson Counties for outpatient endoscopy, including Mission's own facilities in Asheville. Park Ridge, which recently spent $26 million upgrading its surgical services, offers outpatient endoscopy in a state of the art facility, is only a few miles from Mission's proposed location in Fletcher. *See* Exhibit E.

On page 73 of the application, the State asks Mission to

> *Explain and provide specific documentation of the inadequacy or inability of existing providers to meet the need identified by the applicant.*

In response to this question, Mission does not discuss the inadequacy or inability of existing providers to meet the need identified by the applicant. Instead, Mission says the project will provide "better geographic access to services by Mission." *See* application, page 73. As discussed above, there is no evidence in the application demonstrating that patients have difficulty accessing endoscopy services where they are presently located, including at Mission, so Mission's claim that Mission GI South will provide "better access" to Mission's services is unsubstantiated. In fact, as noted above, two of Mission's service area zip codes, 28806 and 28803, are adjacent to 28801, where Mission is located.

Mission GI South unnecessarily duplicates other facilities that offer outpatient endoscopy. Thus, the application is non-conforming with Criterion 6. *See also* Exhibit A (Wake Forest Ambulatory Ventures findings).

VI. THE APPLICATION FAILS TO SATISFY CRITERION 7.

The application fails to conform to Criterion 7 because the staffing is incomplete. Page 9 of the application states Mission GI South will have anesthesia conscious sedation, business office functions, reception and on-site registration. But the staffing tables in Section VII of the application omit these positions.

VII. THE APPLICATION FAILS TO SATISFY CRITERION 12.

The application fails to conform to Criterion 12 because the line drawings in Exhibit 6 are unlabeled and incomplete. Within the "Area of Construction" shown in Exhibit 6, Mission shows a "black box" that may be the endoscopy room, but since nothing is labeled, it is impossible to know for sure. Nor is it possible to tell what is inside the "black box." The line drawings show no entrance from the building exterior, no patient waiting area and no registration area. The line drawings in Exhibit 6 and the "conceptual cost estimate" in Exhibit 29 fail to demonstrate that the proposed GI endoscopy procedure room will be constructed to meet hospital licensure rules and construction requirements.

On page 110 of the application, Mission refers to an MOB exemption letter to be filed by an unknown property developer. In Exhibit 29, the architect refers to an "80,000 sf two story MOB, developed by PMR, dated 3/09/11." Exhibit 29 contains an unclear site plan, so it is not possible to know what else is in the MOB. It appears that the "conceptual cost estimate" is based on certain amounts being allocated to the MOB and not to the endoscopy room. Since the architect's letter does not explain the basis for the allocation, it is impossible to know if this "conceptual cost estimate" is accurate.

VIII. THE APPLICATION FAILS TO SATISFY CRITERION 18a.

Criterion 18a of the CON Law requires the applicant to demonstrate the effects of its proposal on competition. A project that is not needed, like this one, does not have a positive impact on competition. Typically, when an application is non-conforming with Criterion 3, it will also be found non-conforming with Criterion 18a. *See* Exhibit A (Wake Forest Ambulatory Ventures findings).

On page 84 of the application, the applicant is asked to

> *Describe how the proposed project will foster competition.*

Mission answers that the project is necessary to improve the delivery of GI endoscopy services by Mission. Mission also repeats many of the statements it made previously about expanding access and choice, population growth and travel to downtown Asheville. Mission then states:

> *Mission will equal or surpass other providers in the region in terms of promoting cost effectiveness, quality and access to care. These efforts will allow Mission to remain competitive in the western North Carolina health care market. Mission aims to improve the health of the people of western North Carolina.*

Mission fails to tell the Agency that on March 1, 2011, the State of North Carolina published a study by Gregory S. Vistnes, Ph.D., an economist hired by DHSR and the Attorney General's Office to analyze Mission's behavior under its Certificate of Public Advantage (COPA) that was issued to Mission in 1998. The COPA, which allowed Mission to merge with its formal rival, St. Joseph's Hospital, places certain limitations on Mission's activities. The report, entitled *An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health*, is attached as Exhibit K. A copy of the COPA is found in Exhibit L.

In the report, Dr. Vistnes describes numerous problems with the COPA, and noted that the COPA gives Mission incentives to raise outpatient prices. The report also acknowledges that the COPA may give Mission an unfair advantage relative to other providers. Dr. Vistnes makes several recommendations in the report about modifications to the COPA. DHSR and the Attorney General's Office are the process of reviewing the Vistnes report and the comments submitted on the report. Presumably, these Agencies will decide whether to modify the COPA in the near future.

While the CON Section is not an antitrust regulatory body, it is important to consider the Vistnes report in the context of this application. The fact that Mission is seeking to move an endoscopy room to the Buncombe/Henderson border, when there clearly is no community need to do so, suggests that Mission's goal is twofold: (1) to shift volume from existing

providers of outpatient endoscopy services, including Park Ridge; and (2) establish a presence in Henderson County so that it can increase its market share in Henderson County, not only for outpatient endoscopy but also for other services. It is no coincidence that the location chosen for Mission GI South is about five miles from Park Ridge's front door. While Mission states that the project will be in Buncombe County, the deed to the property shows that part of the property on which Mission GI South is located is actually in Henderson County. *See* Exhibit 28 to the application.

While Mission steadfastly maintains it is only planning on shifting some of its own volume from Mission's main campus to Mission GI South, and that this project will not negatively impact other providers, *see, e.g.,* application pages 32 and 58, this claim is contradicted by the fact that Mission's outpatient endoscopy volumes are declining. Since its own endoscopy volumes are going down, Mission cannot keep this endoscopy room busy if it does not attempt to shift volumes from other providers, including Park Ridge, which recently spent $26 million upgrading its own facilities. Loss of patients in turn means lost revenue for these other providers, including Park Ridge. The Henderson County line location of Mission GI South gives Mission another opportunity to increase its Henderson County market share, which has been climbing steadily since 2005. *See* Table 1 to Vistnes Report in Exhibit D. The fact that Mission is proposing to move this endoscopy room to the Buncombe/Henderson border (*see* Exhibits 6, 28 and 29 to the application) further indicates that its patient origin at Mission GI South is not going to be "the same" as it is today. *See* application, pages 70 and 71.

Mission also has much bigger plans for Fletcher than simply the relocation of one endoscopy room. The attached email from Ron Paulus, M.D., CEO of Mission, shows that Mission plans a "Fletcher health campus." *See* Exhibit M. The endoscopy room relocation is apparently the first step toward developing this "campus," just a few miles from Park Ridge's front door. The application, of course, does not discuss the "campus."

This is not just ordinary competition at work. As the Vistnes report notes, Mission is a monopolist that has substantial incentives under the COPA to engage in regulatory evasion through the expansion of outpatient services in other geographies, *i.e.*, Mission has strong motives to find ways to get around the COPA so that it can exercise market power to the detriment of health care consumers and other providers in Western North Carolina. This project, which certainly cannot be justified on the basis of community need or Mission's own volumes, does nothing to foster competition.

Thus, the application is non-conforming with Criterion 18a. *See also* Exhibit A (Wake Forest Ambulatory Ventures findings).

CONCLUSION

For the reasons stated above, the Mission GI South CON application is non-conforming with multiple review criteria and should be denied.

EXHIBIT

A

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."*

<u>*Advances in Ambulatory Surgery and Regulatory Changes*</u>

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 <u>not</u> 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.

.2103(e) *An applicant proposing 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) provide documentation to show that each existing ambulatory surgery program in the service area that performs ambulatory surgery in the same specialty area as proposed in the application is currently utilized an average of at least 1,872 hours per operating room per year, excluding dedicated open heart and C-Section operating rooms. The hours utilized per operating room shall be calculated as follows: [(Number of projected inpatient cases, excluding open heart and C-sections performed in dedicated rooms times 3.0 hours) plus (Number of projected outpatient cases times 1.5 hours)] divided by the number of operating rooms, excluding dedicated open heart and C-Section operating rooms; and

-NC- The applicant states that plastic surgery will be one of the specialties at the proposed multi-specialty ASF. PSCNC is the only existing ambulatory surgical program in the service area (Forsyth County). It is a single specialty ambulatory surgical program. The applicant did not provide documentation to show that the three ORs at PSCNC are currently utilized an average of at least 1,872 hours per operating room per year. In fact, in the 2010 SMFP, the facility identified is identified as "chronically underutilized." See page 74 in the 2010 SMFP. Therefore, the application is nonconforming to this Rule.

(2) demonstrate the need in the third operating year of the project based on the following formula: [Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1,872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need for the conversion is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-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(f) *The applicant shall document the assumptions and provide data supporting the methodology used for each projection in 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, projected utilization is not based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming to this Rule.

.2104 SUPPORT SERVICES

.2104(a) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide copies of the written policies and procedures that will be used by the proposed facility for patient referral, transfer, and follow-up.*

-NA- The applicant proposes to relocate an existing ASF, change its name and convert it from single specialty to multi-specialty. This Rule is not applicable.

.2104(b) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital shall provide documentation showing the proximity of the proposed facility to the following services:*

(1) emergency services;
(2) support services;
(3) ancillary services; and
(4) public transportation.

-NA- The applicant proposes to relocate an existing ASF, change its name and convert it from single specialty to multi-specialty. This Rule is not applicable.

.2105 STAFFING AND STAFF TRAINING

.2105(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 increase the number of operating rooms in a facility, 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, justify and document the availability of the number of current and proposed staff to be utilized in the following areas:*

(1) administration;
(2) pre-operative;
(3) post-operative;
(4) operating room; and
(5) other.

-C- In Section VII.2, page 74, the applicant provides documentation of the availability of the proposed staff to be utilized in each of the areas listed in this Rule.

.2105(b) *The applicant shall identify the number of physicians who currently utilize the facility and estimate the number of physicians expected to utilize the facility and the criteria to be used by the facility in extending surgical and anesthesia privileges to medical personnel.*

-C- In Section VII.9(b), pages 104-105, the applicant provides the number of WFUHS physicians expected to utilize the proposed facility. On page 104, the applicant states,

> *"The projected number of active medical staff is based on the list of physicians that have expressed willingness to perform procedures and professional services at the new facility. These and additional physicians will have the opportunity to apply for medical staff privileges and perform services at the proposed facility in accordance with the medical staff by-laws and their individual scope of privileges and in compliance with the Certificate of Need operating room regulations."*

Additionally, Exhibit 9 contains a copy of the physician credentialing criteria. In Section III.1(b), page 35, the applicant states there are no physicians currently utilizing PSCNC.

.2105(c) *The applicant shall provide documentation that physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the service area in which the facility is, or will be, located or documentation of contacts the applicant made with hospitals in the service area in an effort to establish staff privileges.*

-C- Exhibit 16 contains a letter from Andrea S. Fernandez, M.D., medical director for the proposed facility, that states,

> *"As the Medical Director for Clemmons Medical Park ASC, I have responsibility for ensuring that the physicians with privileges to practice in the facility are active members in good standing at a general acute care hospital or will have written referral procedures*

with a physician who is an active member in good standing at a general acute care hospital in the ambulatory surgical service area."

The WFUHS surgeons are members of NCBH's medical staff. NCBH is an acute care hospital located in the service area (Forsyth County).

.2105(d) *The applicant shall provide documentation that physicians owning the proposed single specialty demonstration facility will meet Emergency Department coverage responsibilities in at least one hospital within the service area, or documentation of contacts the applicant made with hospitals in the service area in an effort to commit its physicians to assume Emergency Department coverage responsibilities.*

-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.

.2106 *FACILITY*

.2106(a) *An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital shall demonstrate that reporting and accounting mechanisms exist and can be used to confirm that the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

-NA- The applicant does not propose to establish a licensed ambulatory surgical facility that will be physically located in a physician's or dentist's office or within a general acute care hospital.

.2106(b) *An applicant proposing a licensed ambulatory surgical facility or a new hospital shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.*

-C- The applicant states the proposed ASF will seek accreditation from the Accreditation Association for Ambulatory Health Care (AAAHC) once operational.

.2106(c) *All applicants shall document that the physical environment of the facility to be developed or expanded conforms to the requirements of federal, state, and local regulatory bodies.*

-C- Exhibit 10 contains a letter from Tabor Architecture, the architects for the proposed project, which documents that the physical environment will conform to the requirements of federal, state, and local regulatory bodies.

.2106(d) *An applicant proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital shall provide a provide a floor plan of the proposed facility identifying the following areas:*

(1) receiving/registering area;
(2) waiting area;
(3) pre-operative area;
(4) operating room by type;
(5) recovery area; and
(6) observation area.

-C- In Exhibit 11, the applicants provide a copy of the floor plan for the proposed facility, which identifies the specific areas required by this Rule.

.2106(e) *An applicant proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or by adding a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility shall demonstrate the capability of the existing ambulatory surgical program to provide the following for each additional specialty area:*

(1) physicians;
(2) ancillary services;
(3) support services;
(4) medical equipment;
(5) surgical equipment;
(6) receiving/registering area;
(7) clinical support areas;
(8) medical records;
(9) waiting area;
(10) pre-operative area;
(11) operating rooms by type;
(12) recovery area; and
(13) observation area.

-NA- The applicant proposes to develop a new ambulatory surgical facility.

EXHIBIT
B

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: November 24, 2010
FINDINGS DATE: December 2, 2010

PROJECT ANALYST: Gregory F. Yakaboski
TEAM LEADER: Martha J. Frisone

PROJECT I.D. NUMBER: J-8529-10/ Duke University Health System d/b/a Duke Raleigh Hospital/ Acquire a second fixed MRI scanner to be located in the hospital in Raleigh/ Wake County

J-8537-10/ North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs/ Acquire a fixed MRI scanner to be located in a new diagnostic center in Holly Springs/ Wake County

J-8534-10/ Wake Radiology Diagnostic Imaging, Inc. and Wake Radiology Services, LLC/ Acquire a fixed MRI scanner to be located in an existing diagnostic center in Garner/ Wake 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.

C – Duke Raleigh
NC- NCDI- Holly Springs
NC- Wake Radiology

The 2010 State Medical Facilities Plan (2010 SMFP) provides a methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2010 SMFP identified a need for one additional fixed MRI scanner in Wake County. Three applications were submitted to the Certificate of Need Section, each proposing to acquire a fixed MRI scanner for Wake County. Each proposal is briefly described below.

Duke University Health System d/b/a Duke Raleigh Hospital ("Duke Raleigh") currently owns and operates one (1) fixed MRI scanner on the Duke Raleigh Hospital campus. In addition, Duke Raleigh offers mobile MRI services through a contract with Alliance HealthCare Services ("Alliance") 36 hours per week. The applicant states the contract for mobile MRI services would be terminated if the proposal is approved. The applicant proposes to acquire no more than one fixed MRI scanner to be located in Wake County. Consequently, the application is conforming to the need determination in the 2010 SMFP.

North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs ("NCDI- Holly Springs") proposes to acquire a fixed MRI scanner and develop a new diagnostic center in leased space at 190 Rosewood Centre Drive in Holly Springs. The applicant proposes to acquire no more than one fixed MRI scanner to be located in Wake County. Consequently, the application is conforming to the need determination in the 2010 SMFP.

Wake Radiology Diagnostic Imaging, Inc. ("WRDI") and Wake Radiology Services, LLC ("WRS") together ("Wake Radiology") Wake Radiology proposes to acquire a fixed MRI scanner and locate it in an existing diagnostic center in Garner. WRS would acquire and install the proposed fixed MRI scanner and WRDI would operate the proposed fixed MRI scanner. Wake Radiology currently offers mobile MRI services at Wake Radiology Garner Office ("WRGO") through contracts with Alliance and Wake Radiology Diagnostic Imaging (one of the co-applicants). The applicants state the contracts for mobile MRI services would be terminated if the proposal is approved. The applicants propose to acquire no more than one fixed MRI scanner to be located in Wake County. Consequently, the application is conforming to the need determination in the 2010 SMFP.

In addition, Policy GEN-3 in the 2010 SMFP is applicable to the review of these proposals. Policy GEN-3 states:

> *"A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area."*

The applicants responded to Policy GEN-3 as follows:

Duke Raleigh – Promote Safety and Quality

In Section II.7(a), pages 9-10, the applicant describes the methods to be used to promote safety and quality care as follows:

> *"Quality Management Program*
>
> *The DRAH quality management program emphasizes a customer-oriented perspective that is used by each department to determine the needs of patients, physicians and others that use the hospital's services. Each department strives to meet or exceed customer's expectations.*
>
> *Direction for Quality Improvement comes from the Performance Improvement Council (PIC), which identifies PI projects for DRAH. The PIC consists of members of the DRAH medical staff, department directors and administrative staff. The goal of using the FOCUS PDCA methodology has been to standardize the quality improvement process throughout DRAH, joining clinical and non-clinical quality efforts with a process that can be easily implemented, measured and maintained. Please see Exhibit II.7 for copies of the following documents relating to DRAH's efforts to ensure quality care:*
>
> - *FY2010 Organizational Performance Improvement Plan and Patient Safety Plan*
> - *Utilization Management Plan*
>
> *Patient Satisfaction Research*
>
> *DRAH understands the importance of soliciting, analyzing, and understanding customer feedback regarding the provision of healthcare services. Since 1999 DRAH has contracted with Press-Ganey to conduct random patient satisfaction surveys. Patients who use inpatient, outpatient, surgical and ED services are surveyed post-discharge. Results from these patient satisfaction surveys are shared with all managers and employees of DRAH to assist in improving services. Moreover, survey results provide invaluable feedback on all aspects of hospital services, both clinical and operational, and they are used in staff and manager performance evaluations and in determining merit increases."*

Duke Raleigh adequately demonstrates that it will promote safety and quality in the delivery of the proposed services.

Promote Equitable Access

In Section VI.2, page 44, the applicant states:

> *"The services of Duke Raleigh Hospital are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, referral, or emergency* [sic] *basis "*

See Criterion (13) for additional discussion. Duke Raleigh adequately demonstrates it will promote equitable access to the proposed services for patients with limited financial resources and other medically underserved persons.

Maximize Healthcare Value

In Section X.1, page 71, the applicant states:

> *"The project proposed in this application has been designed to reduce to a minimum the cost of developing and operating the MRI scanner proposed in this application by:*
>
> *1) The exercise of tight control over the renovation plans. (See the response to Section VIII.1 (b) for additional information.)"*
> *2) Minimizing the disruption of existing services during the renovation and installation process.*
> *3). Integrating the operation of the proposed MRI scanner with that of the existing MRI scanner.*
> *4) Completing the project as quickly as possible to allow the earliest possible termination of the mobile scanner service."*

The applicant adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) for discussion. Therefore, the applicant adequately demonstrates that the proposal would maximize healthcare value. Furthermore, the applicant adequately documents how its projected volumes incorporate these concepts in meeting the need identified in the 2010 SMFP as well as addressing the needs of all residents of the service area.

In summary, the application is consistent with Policy GEN-3 and conforming to the need determination in the 2010 SMFP. Consequently, the application is conforming to this criterion.

NCDI- Holly Springs – Promote Safety and Quality

In Section II.7(a), pages 18-19, the applicant describes the methods to be used to promote safety and quality care as follows:

> *"NCDI-Holly Springs will use several methods to ensure and maintain quality care at its facility. All facilities managed by MedQuest are required to adhere to the company's quality assurance plan, which includes continuous quality improvement.*
>
> - *NCDI-Holly Springs will seek and obtain accreditation for the proposed equipment. This ensures that quality images are produced by the unit for all types of scans.*

- *NCDI-Holly Springs will have preventive maintenance recommended by the manufacturer performed on the unit pursuant to original equipment manufacturer ("OEM") specifications.*

- *All radiologists who interpret scans for NCDI-Holly Springs will be board-certified. These radiologists will set protocols for scans performed by NCDI-Holly Springs. They also will follow ACR guidelines for communication in issuing reports.*

- *NCDI-Holly Springs's technologists will be certified by the American Registry of Radiologic Technologists (ARRTS) or will be required to obtain ARRT certification within one year of their employment with NCDI-Holly Springs. Any technologists who have not received certification will work under the supervision of a registered technologist. All NCDI-Holly Springs technologists will be required to receive ongoing continuing medical education to stay current on relevant clinical issues. All NCDI-Holly Springs technologists will also be trained in CPR.*

- *NCDI-Holly Springs will provide 24 to 48 hour radiology report turnaround to referring physicians to ensure that treatment and the cycle of care are not delayed.*

- *NCDI-Holly Springs representatives will meet with referring physicians to obtain feedback on image quality, radiology report quality, convenience of scheduling and accessibility, and patient experience. NCDI-Holly Springs will react to this feedback quickly to ensure that the needs of referring physicians are met. NCDI-Holly Springs will also survey a sample of patients on a monthly basis to obtain feedback on patient experiences at the facility.*

- *NCDI-Holly Springs will be regularly inspected by Medicare and must pass Medicare inspection, including applicable IDTF regulations, in order to participate in the Medicare program.*

The MedQuest Quality Assurance Plan is provided as Attachment 9.

In addition to the quality controls set forth by MedQuest, NCDI-Holly Springs will provide high clinical quality through its relationship with its Medical Director, Dr. David Wiener. Dr. Wiener is a board-certified radiologist and maintains all continuing medical education requirements. As Medical Director, Dr. Wiener will be responsible for all clinical decisions affecting the care provided to patients. Please see Attachment 10 for Dr. Wiener's curriculum vitae and Attachment 11 for a letter expressing Dr. Wiener's willingness to serve as Medical Director. Dr. Wiener and his associates at Durham Radiology will provide interpretation services for NCDI-Holly Springs."

NCDI- Holly Springs adequately demonstrates that it will promote safety and quality in the delivery of the proposed services.

Promote Equitable Access

In Section VI.2, page 91, the applicant states *"NCDI- Holly Springs will not discriminate based on race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay. NCDI- Holly Springs will be committed to providing necessary medical care to any individual regardless of that person's ability to pay."* See Criterion (13) for additional discussion. NCDI- Holly Springs adequately demonstrates it will promote equitable access to the proposed services for patients with limited financial resources and other medically underserved persons.

Maximize Healthcare Value

In Section X.1, page 123, the applicant states:

> *"Special efforts by NCDI- Holly Springs to contain the costs of offering the proposed outpatient imaging services include, but are not limited to:*
>
> - *NCDI- Holly Springs is working closely with the equipment vendor to secure the most cost effective pricing for the proposed equipment.*
> - *NCDI- Holly Springs is leasing space in an existing building, instead of building a new building.*
> - *NCDI- Holly Springs is proposing to renovate space in an existing facility rather than to construct a new facility for the proposed MRI scanner."*

However, NCDI- Holly Springs did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) for discussion. Therefore, NCDI-Holly Springs did not adequately demonstrate that the proposal would maximize healthcare value.

In summary, the application is not consistent with Policy GEN-3. Consequently, the application is nonconforming to this criterion.

Wake Radiology – Promote Safety and Quality

In Section II.7(a), pages 25-26, the applicants describe the methods to be used to promote safety and quality care as follows:

> *"Providing quality patient care and rendering services in an effective and efficient manner is the goal of WRDI's ongoing performance improvement process. This quality assurance process is designed to objectively measure and improve patient care activities and services in order to identify opportunities for improvement.*

Consistent with the existing fixed MRI scanners at Raleigh MRI and the mobile MRI scanner operated by WRDI, the proposed fixed MRI scanner will be accredited by the American College of Radiology (ACR). The ACR awards accreditation to facilities for the achievement of high practice standards after a peer-review evaluation of the practice. Evaluations are conducted by board-certified physicians and medical physicists who are experts in the field. They assess the qualifications of the personnel and the adequacy of facility equipment. WRDI's existing accreditations are indications of the ongoing commitment to quality. Please refer to Exhibit 17 for copies of current ACR accreditation certificates.

WRDI seeks to provide an optimal, uniform level of care by reducing and/or eliminating unnecessary and correctable risks, hazards, and expense. Thus, WRDI has an established Risk Management plan. The program includes activities designed to ensure patient safety, reduce accidents, and conserve financial resources.

WRDI also has an established Medical Review Committee to monitor the quality of care provided by Radiologists and staff, and to make recommendations to improve the quality, cost, appropriateness or necessity of health care services. Please refer to Exhibit 5 for policies and procedures of the Medical Review Committee.

A Radiologist Peer Review Policy is also in place as part of the Medical Review Committee. This process encompasses ultrasound, MRI, CT, nuclear medicine, bone density and mammography/breast MRI pathology. The process meets all ACR requirements. Please refer to Exhibit 5 for copies of WRDI's Peer Review Policy."

Wake Radiology adequately demonstrates that it will promote safety and quality in the delivery of the proposed services.

Promote Equitable Access

In Section VI.2, page 109, the applicants state:

> *"WRDI will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Diagnostic imaging services at WRDI's Garner MRI facility will continue to be available to and accessible by any patient having a clinical need for those services."*

See Criterion (13) for additional discussion. Wake Radiology adequately demonstrates it will promote equitable access to the proposed services for patients with limited financial resources and other medically underserved persons.

Maximize Healthcare Value

In Section X.1, page 129, the applicants state:

"The provision of MRI services via WRDI's proposed fixed MRI scanner will provide a more cost effective way to bring services closer to the WRDI patients and other residents of the service area who utilize them. The location of MRI services in the Garner Office facility is more cost effective than diagnostic imaging services provided in a hospital setting in Wake County. The operations of the fixed MRI scanner also will be less costly than the current mobile MRI service because WRDI will reduce equipment rental costs associated with a third-party mobile equipment vendor.

WRDI is committed to and will be actively involved in efforts to contain costs in its facility. WRDI will develop the project in the most cost-effective manner. Examples of cost-saving measures include:

- *The proposed new imaging system is modern technology and will improve scan speed, image quality and capabilities. This enhanced capacity will enable more procedures per day, ultimately reducing the cost per scan.*

- *Because the proposed project is located at an existing medical clinic, staffing and operational costs are minimal, as WRDI will utilize staff and space quite efficiently.*

For CON purposes, WRS and WRDI estimated the capital costs conservatively to avoid a project cost overrun. Actual costs may be less. WRS will obtain competitive vendor quotations for the proposed new fixed MRI scanner."

However, Wake Radiology did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) for discussion. Therefore, Wake Radiology did not adequately demonstrate that the proposal would maximize healthcare value.

In summary, the application is not consistent with Policy GEN-3. Consequently, the application is nonconforming to this criterion.

One fixed MRI scanner is the limit on the number of MRI scanners that may be approved for this review. See the Comparative Analysis section for the decision regarding development of an additional fixed MRI scanner in Wake County.

(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.

C – Duke Raleigh
NC- NCDI-Holly Springs
NC- Wake Radiology

Duke Raleigh currently owns and operates one (1) fixed MRI scanner on the Duke Raleigh Hospital campus. The applicant proposes to acquire a second fixed MRI scanner which will be located on the Duke Raleigh Hospital Campus.

Population to Be Served

In Section III.5(a), page 32, the applicant states "*As recent experience appears the best predictor of future patterns, we project the same geographic service area for future MRI services as our current service area.*" In Section III.4(b), page 31, the applicant provides the current and projected patient origin for the MRI services provided at Duke Raleigh Hospital, as shown in the table below:

County	FY2009 Percent of Total	FY2012-2013 Percent of Total
Wake	76.8%	76.8%
Johnston	5.0%	5.0%
Franklin	5.2%	5.2%
Harnett	1.7%	1.7%
Other NC Counties	9.8%	9.8%
Other States	1.5%	1.5%

The applicant adequately identified the population proposed to be served.

Need Analysis

Duke Raleigh has one (1) existing fixed MRI scanner. In Section III.1, pages 27-29, the applicant states that the need for the proposed second fixed MRI scanner at Duke Raleigh Hospital is based on the following factors:

> *"The urgent need for the additional fixed MRI scanner proposed in this application is documented in the following places:*
>
> 1) *Thomson Reuters' population projections. The primary service area for MRI services at Duke Raleigh Hospital is Wake County, with nearly 77% of patients originating within the county. The secondary service area includes Franklin and Johnston counties, each with approximately 5% of the total MRI volume. Population within these counties is expected to increase significantly between 2009 and 2014 as illustrated below.*

Service Area Population Projections

County	2009	2010	2011	2012	2013	2014	CAGR
Wake	920,760	949,171	978,459	1,008,651	1,039,774	1,071,858	3.1%
Johnston	136,394	139,934	143,565	147,291	151,113	155.035	2.6%
Franklin	54,949	56,193	57,465	58,766	60,096	61,457	2.3%
Grand Total	1,112,103	1,145,298	1,179,490	1,214,708	1,250,984	1,288,350	3 0%

Source: Thomson Reuters

Moreover, Wake County's population is aging rapidly. Projections provided by Thomson Reuters suggest that between 2009 and 2014 the population age 65+ will grow more than 40%, and the population age 45-64 will grow more than 20%. People in these age groups are far more likely to be referred for MRI scans than people in younger age groups.

2) *The 2010 State Medical Facilities Plan, which finds need for an additional fixed MRI scanner in Wake County. That finding results from the fact that the number of unweighted procedures provided in Wake County increased nearly 10% over the last 3 years, while the total provided in the entire state remained virtually unchanged:*

Unweighted Procedures Provided in Wake County

Year	Wake County	State
2007	65,582	821,829
2008	65,892	814,048
2009	72,036	822,853
% Change	9.8%	0.1%

We believe that the difference reflects both the growth and aging of the Wake County population and the growing migration of acute care patients from the rural counties where they live to the largest urban counties for treatment, especially for specialty and inpatient care. During FY2009, the MRI scanners at Duke Raleigh provided procedures for residents of 70 of the state's 100 counties. We believe that both trends will continue.

3) *The 25% increase in the volume of weighted MRI procedures provided at Duke Raleigh over the last 3 years:*

MRI Scans Provided at Duke Raleigh Hospital

Year	Unweighted Procedures	Weighted Procedures
FY2007	3,884	4,864
FY2008	4,071	5,212
FY2009	4,634	6,070
% Change	19.3%	24.8%

The growth reflects the recruitment of additional physicians, especially subspecialists from Duke University Medical Center supporting the Duke Raleigh Hospital's service lines in neuroscience, musculoskeletal, oncology,

and cardiac services. Their impact is reflected in the growth in admissions, patient days, outpatient visits to the campus, surgical procedures, and other services as well as MRI services.

As the new physicians continue to ramp up their practices on the campus, their MRI referrals are sure to increase. (See the letters of support in Exhibit V.3.) Despite the addition of a third mobile day, current capacity will not be able to accommodate growth at the rates of the last two years. Thus the growth rate projected for the interim year (FY2011) is a modest 7.4% [sic]

4) *The continuing increase in the number of surgical procedures performed at Duke Raleigh. Between FY2008 and FY2009, the number of inpatient procedures increased 28%, and the number of ambulatory procedures grew 18%. Through the first 10 months of FY2010, the Hospital was providing inpatient procedures at the rate of 3;462 per year, an increase of 15.2% over FY2009, and ambulatory procedures at the rate of 11,402 per year, an increase of 5.4% over FY2009.*

5) *A physician recruitment plan that projects the Hospital bringing on 25 specialists, including 14 additional surgeons, between July 1, 2010 and June 30, 2015. Those totals do not include Raleigh surgeons now applying for privileges for the first time, and the recruitment schedule (See Exhibit VII.6) underestimates the speed with which recruits are being identified and brought on board. For instance, the neurosurgeon slated to begin practicing in FY2013 will begin in FY2011.*

   As surgeons are especially likely to order MRI procedures, their recruitment will certainly increase the utilization of the Hospital's MRI scanners.

6) *The current backlog of patients awaiting MRI procedures. Even though the Hospital's existing fixed MRI scanner is staffed and available 106.5 hours per week and the mobile scanner provides service 3 full days (36 hours) each week, non-emergent patients, especially those needing scans of the quality provided by the fixed MRI scanner, are frequently obliged to wait a week or more for their MRI procedures.*

7) *The projections provided by Sg2, a national health care consulting firm that uses current data, trends, and sophisticated models to project county-specific utilization rates. Sg2 anticipates that the demand for MRI procedures will increase 28.1% in Wake County between 2010 and 2014, or approximately 6.1% per year.*

Given those facts and the fact that the Hospital is on track to exceed virtually all its utilization projections for the current year, our projection that the number of procedures provided by the Hospital's MRI scanners will increase by an average of less than 10% per year over the years from FY2010 through FY2014 appears

conservative."

Historical and Projected Utilization

In Section IV, pages 35-37, the applicant provides historical and projected MRI scanner utilization, as illustrated in the table below.

	Prior Full FY2007	Prior Full FY2008	Last Full FY2009	Interim Full FY2010	Interim Full FY2011	First Full FY2002	Second Full FY2013	Third Full FY2014
# of Fixed MRI Scanners	1	1	1	1	1	2	2	2
#of Procedures	3,884	4,071	4,634	5,476	5,880	6,654	7,269	8,034
# of Weighted Procedures	4,864	5,212	6,070	7,181	7,712	8,728	9,534	10,538
Average # of Weighted Procedures	4,864	5,212	6,070	7,181	7,712	4,364	4,767	5,269

As shown in the table above, during FY2009, the existing fixed MRI scanner and the mobile MRI scanner performed a total of 6,070 weighted MRI procedures. During the third project year, the applicant projects that the two fixed MRI scanners will perform an average of 5,269 weighted MRI procedures per scanner, which exceeds the 4,805 required by 10A NCAC .2703(b)(3).

In Section IV.1(d), pages 36-37, the applicant provides the assumptions and methodology used to project utilization for MRI services and states

> *"The substitution of a second fixed MRI scanner operating 70 hours per week (or more, as necessary) for a mobile scanner operating 36 hours per week will give the Hospital 34 hours of additional scan time each week. How will that capacity be used?*
>
> 1) *First, to accommodate growth attributable to the projected increase in MRI utilization. Sg2, a national health care consulting firm specializing in the analysis of technology utilization, predicts that MRI utilization in Wake County will increase, on average, 6.1% per year through FY 2014. Growth at that rate would increase the annual volume at Duke Raleigh from a projected 5,476 unweighted procedures in FY 2010 to a projected 6,943 unweighted procedures in FY 2014:*

	FY2010(Proj)	*FY2011*	*FY2012*	*FY2013*	*FY2014*
Inpatient	*897*	*958*	*981*	*1,009*	*1,041*
Outpatient	*4,579*	*4,853*	*5,185*	*5,534*	*5,902*
Total	*5,476*	*5,811*	*6,166*	*6,543*	*6,943*

> 2) *Second, to accommodate patients that physicians practicing on the Hospital campus now send to fixed MRI scanners elsewhere to avoid the delays (of as*

much as a week or more) resulting from the intensive utilization of the fixed MRI scanner at the Hospital. It is not possible to determine with certainty the number of patients now referred elsewhere, but anecdotal evidence suggests about 6 per week. If the Hospital's MRI service were to continue with a single fixed MRI scanner and a mobile MRI 36 hours per week, that number would also grow 6.1% per year through FY 2014:

	FY2010(Proj)	FY2011	FY2012	FY2013	FY2014
Total	315	334	355	376	399

While the Hospital will not pick up this volume until FY2012, when the new fixed MRI scanner would become operational, we project a small portion of this volume in FY2011 will be accommodated with the addition of the 3rd mobile MRI day.

3) *Third, to accommodate the additional procedures that we can safely predict that the 31 physicians to be recruited will order. To calculate the totals below, we assumed that:*

- *The physicians would all begin practice on the first day of the fiscal year that they are scheduled to start;*
- *Their order rates would increase 50% per year over four years.*
- *In the fourth year of their practice on the campus, their order rates would be the same as those for physicians in the same subspecialties now well established at the Hospital (as many as 290 per year for a neurologist to as few as 5 for a pulmonologist); and*
- *For recruits in subspecialties not yet well established on the campus (e.g., oncologic surgery), the order rates would be the same as the order rates of physicians in the same subspecialties practicing at Duke.*

	FY2011	FY2012	FY2013	FY2014
Total	221	487	727	1,092

Finally, to derive the total procedures to be provided each year, we subtracted from the procedures attributable to the recruits the procedures attributable to the growth attributable to the projected increase in MRI utilization. That is reflected in the table below, which shows on line 3 the procedures over and above those attributable to population growth that the recruits will order.

Duke Raleigh MRI Volume Projections

	FY2010(Proj)	FY2011	FY2012	FY2013	FY2014
1)	5,476	5,811	6,166	6,543	6,943
2)	—	69	355	376	399
3)	—	—	133	350	692
Unweighted	5,476	5,880	6,654	7,269	8,034
Weighted	7,181	7,712	8,728	9,534	10,538

In the public hearing on the Hospital's two additional operating rooms, the President of Duke Raleigh noted that the number of surgeons practicing at the Hospital is continuing to increase because of applications for privileges from physicians already established in Raleigh. The projections provided here do not include any additional MRI procedures, over and above those attributable to the growth in projected MRI utilization, attributable to those additional physicians."

To determine projected utilization, the applicant used FY2010 as the base year and applied an annual growth rate of 6.1%. As illustrated in the table below, between 2004 and 2009, the compound annual growth rate ("CAGR") for unweighted MRI procedures performed in Wake County was 8.1%. In FY2009 and FY2010, the number of unweighted MRI procedures performed at Duke Raleigh Hospital increased 13.8% [4,634 FY09/ 4,071 FY08 = 1.138 or 13.8% growth] and 18.2% [5,476 FY10 / 4,634 FY09 = 1.181 or 18.1% growth], respectively.

Wake County Historical MRI Utilization FY2004 – FY2009

	Unweighted MRI Scans	Weighted MRI Scans
FY2004	48,815	57,537
FY2005	53,122	62,174
FY2006	55,692	65,936
FY2007	65,582	77,172
FY2008	65,892	77,428
FY2009	72,036	86,533
04-09 CAGR	8.1%	8.5%

The applicant used a lower rate (6.1%) than the Wake County CAGR from 2004-2009 (8.1%) or the percentage increases at Duke Raleigh Hospital (13.8% and 18.2%). Next, the applicant determined the annual number of MRI procedures that would have been performed at Duke Raleigh Hospital if an appointment had been available in a timely manner (i.e., the ordering physician sent the patient elsewhere), which the applicant states is approximately 6 per week. This number is also increased 6.1% per year. Finally, the applicant determined the annual number of MRI procedures attributed to physician recruitment. To avoid double counting, the applicant states it subtracted projected MRI procedures ordered by physicians already practicing in Raleigh and the increases attributed to the projected 6.1% growth.

Based on these assumptions, the applicant projects it will perform 10,538 weighted MRI procedures in the third project year, which exceeds the 9,610 weighted procedures (4,805 x 2 fixed MRI scanners = 9,610) required by 10A NCAC 14C .2703(b)(3). Projected utilization is based on reasonable and supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire the proposed MRI scanner.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population to be served has for the proposed MRI scanner. Consequently, the application is conforming to this criterion.

NCDI- Holly Springs

NCDI-Holly Springs proposes to acquire a fixed MRI scanner and develop a new diagnostic center at 190 Rosewood Centre Drive in Holly Springs.

Population to Be Served

In Section III.5(b), page 77, the applicant provides projected patient origin for the MRI services to be provided at NCDI- Holly Springs in Project Years 1 and 2, as illustrated in the table below.

NCDI- Holly Springs Projected MRI Patient Origin

County	Number of Patients YR 1	Percentage of Total Patients YR 1	Number of Patients YR 2	Percentage of Total Patients YR 2
Wake	3,082	95.0%	3,522	95.0%
Johnston	32	1.0%	37	1.0%
Lee	32	1.0%	37	1.0%
Chatham	32	1.0%	37	1.0%
Other*	65	2.0%	74	2.0%
Total	3,243	100.0%	3,707	100.0%

*The applicant states "Other" includes: Durham, Orange, Sampson, Duplin, Nash, Craven, Wayne, Vance, Warren, Person, other NC counties and other states.

In Section III.5(c), page 77, the applicant states:

> *"NCDI- Holly Springs is a proposed new facility. NCDI-Holly Springs reviewed the patient data for the mobile MRI host site at NCDI-Cary, which receives services from Kings Medical, an independent third party provider. The majority of patients served at NCDI-Cary originate from Wake County. NCDI-Holly Springs also considered the proximity to other counties near the southern border of Wake County in determining the percentages of patients from other counties. The patient to scan ratio at NCDI-Cary was 1.11 scans per patient. NCDI- Holly Springs utilized this ratio to determine the total number of patients for Years 1 and 2."*

The applicant identifies the population it proposes to serve. However, see discussion below regarding the reasonableness of projecting that residents of Durham, Orange, Sampson, Duplin, Nash, Craven, Wayne, Vance and Person counties would utilize a fixed MRI scanner located in Holly Springs in Wake County given that the proposed facility does not yet exist and the presence of existing fixed and mobile MRI scanners in those counties.

Need Analysis

In Section III.1(a), pages 41-57, the applicant states that the need for the proposed fixed MRI scanner in Holly Springs is based on the following factors:

> *"NCDI- Holly Springs will meet the need for:*

* *Additional fixed MRI capacity based on current and projected demand for MRI services in Wake County;"*

In Section III, page 47, the applicant states *"The population explosion in Wake County is generating increased demand for healthcare services. On a per resident basis, Wake County is greatly underserved considering it is the most populated county in North Carolina. Counting the 2010 need determination for one fixed MRI scanner, there are over 68,000 residents per every one fixed MRI scanner in Wake County. The following chart provides an analysis of the number of residents per fixed MRI scanner in the more populated counties in North Carolina. The average number of residents per fixed MRI scanner in North Carolina is 41,887. The high ratio of residents to fixed MRI scanners could signal a potential issue regarding accessibility to care for patients in Wake County.*

Fixed MRI Scanners Per Residents by County- FY 2009

County	No. of Fixed MRI Scanners	2009 Population	Residents/ 1 Fixed Scanner
Buncombe	10	230,450	23,045
Cabarrus	7	174,294	24,899
Cumberland	7	321,121	45,874
Durham	14	266,189	19,014
Forsyth	17	355,640	20,920
Guilford	11	476,038	43,276
Mecklenburg	18	894,445	49,691
New Hanover	5	194,099	38,820
Orange	9	132,306	14,701
Pitt	7	158,575	22,654
Wake	13	892,607	68,662
North Carolina	224	9,382,610	41,887

Source: Population- NC OSBM; Scan Volume and fixed scanner numbers- Draft 2011 SMFP- Table 9k

* *"Improved access to MRI services for Southern Wake County residents;"*

In Section III, page 47, the applicant states *" The population of the NCDI-Holly Springs Service Area currently exceeds 100,000 persons and is projected to increase by nearly 30,000 persons from 2009 to 2016. The NCDI-Holly Springs Service Area currently represents 11.9% of the total Wake County population and currently none of the 13 existing fixed MRI scanners in Wake County are located there."*

* *"Availability of a fixed MRI in a convenient outpatient setting;"*

In Section III, page 53, the applicant states *"Located in southwest Wake County on N.C. Highway 55, Holly Springs is accessible from U.S. Highway 1, US Highway 64 and US Highway 401. The new N.C. 55 Highway Bypass is a four*

lane median divided, limited access highway that provides direct access to the 400 acre Holly Springs Business Park.

The $21 billion North Carolina General Assembly's spending plan includes $25 million a year for the North Carolina Turnpike Authority's Triangle Expressway project, which would be the state's first toll road and the first phase will open in 2011. The toll road will connect N.C. Highway 147 to N.C. Highway 540, and extend N.C. Highway 540 to Holly Springs (12.6 mile Western Wake Freeway) as shown in the following map. The site for the Holly Springs Surgical Center is strategically located within one mile of the proposed I-540 interchange with Highway 55 Bypass. Construction on the Triangle Expressway in Wake and Durham counties is underway. This 18.8-mile toll road system is a new roadway from the NC 55 Bypass near Holly Springs to I-40 at NC 147 and is comprised of two projects- the Western Wake Freeway and the Triangle Parkway."

* *Lower costs and charges associated with a cost-effective outpatient provider; and*

* *Quality imaging services as provided by Novant and MedQuest for residents of Wake County and the surrounding counties."*

In Section III.1(a), page 43, the applicant states:

"The primary focus for this project is creating improved geographic access to MRI services for residents in southern Wake County and the surrounding areas. Novant and MedQuest are committed to improving the quality and accessibility of healthcare services for the residents of southern Wake County as demonstrated by the numerous CON applications filed by Novant for an acute care facility and operating rooms for this specific area. The proposed NCDI-Holly Springs facility will result in a community-based, locally accessible site for outpatient diagnostic MRI imaging services and brings these services much closer to a population that is underserved in Wake County. If approved, it will be the first fixed MRI scanner in Holly Springs. This is an important consideration in this review, as most fixed MRI scanners in Wake County are clustered in Raleigh or Cary."

Projected Utilization

In Section IV.1, page 82, the applicant provides projected utilization for the proposed fixed MRI scanner through the first three project years, as illustrated in the table below.

NCDI- Holly Springs: Projected MRI Scanner Utilization

	First Full FY (CY 2012)	Second Full FY (CY 2013)	Third Full FY (CY 2014)
# of Units	1	1	1
# of Unweighted Procedures	3,600	4,115	4,661
Percent Change in Unweighted Procedures	-na-	14.3%	13.2%
# of Weighted Procedures	3,881	4,436	5,025
Percent Change in Weighted Procedures	-na-	14.3%	13.2%

As shown in the table above, NCDI-Holly Springs projects that the proposed fixed MRI scanner will perform 5,025 weighted MRI procedures during Project Year 3, which exceeds the 4,805 weighted MRI procedures required by 10A NCAC 14C .2703(b)(3).

In Section III.1, pages 58-68, the applicant provides the assumptions and methodology used to project utilization, as follows:

> *"As a proposed new provider of fixed MRI services in Wake County, NCDI-Holly Springs considered several factors in developing a need methodology for the medically underserved area of southern Wake County. In light of the geographic distribution of MRI scanners in Wake County, NCDI-Holly Springs determined that a location in Holly Springs would increase accessibility to health care services for southern Wake County residents by offering full-time fixed MRI services. After determining that an unmet need existed in southern Wake County and identifying Holly Springs as the most effective location in Wake County for a new fixed MRI scanner, NCDI-Holly Springs developed a need methodology based on population growth and Wake County MRI utilization rates to reasonably project the estimated number of unweighted and weighted MRI scanners* [sic] *for the proposed facility.*
>
> *Step 1: Identify the population to be served* [page 58]

Census Tract	*Town*	*2012*	*2013*	*2014*
532	*Holly Springs*	*39,671*	*41,582*	*43,586*
531.01	*Fuquay Varina*	*19,202*	*20,046*	*20,926*
531.03	*Wake County*	*9,643*	*9,781*	*9,922*
531.04	*Wake County*	*11,547*	*11,892*	*12,247*
534.04	*Holly Springs/Apex*	*21,581*	*22,533*	*23,236*
529	*Wake County*	*15,769*	*16,106*	*16,450*
	Totals	*117,413*	*121,940*	*126,367*

NCDI-Holly Springs selected a site in Holly Springs for numerous reasons. A site in Holly Springs would be easily accessible for the specific census tracts listed above based on its position off of Highway 55. In the defined primary service area, Holly Springs is the most populated area and is projected to continue growing at an accelerated pace. There are currently no fixed MRI scanners located in the primary service area."

Step 2: Determine Wake County Use Rate for MRI Services [pages 59-60]

NCDI-Holly Springs reviewed the annual unweighted volume from FFY 2005 through FFY 2009 to determine the historical MRI use rate per 1,000 population for Wake County.

Wake County- Historical Use Rate (unweighted volume)

Time Period	Unweighted MRI Volume	Wake County Population	Use Rate Per 1,000
FFY 2005	53,122	757,346	70.1
FFY 2006	55,692	793,401	70.1
FFY 2007	65,582	831,537	78.9
FFY 2008	65,808	866,438	75.9
FFY 2009	72,036	892,607	80.7

During FFY 2008, the MRI use rate experienced a slight decrease compared to the previous year. While the growth of MRI utilization has slowed slightly in the FFY 2007-08 time period, NCDI-Holly Springs does not anticipate a continued decrease in MRI utilization as is supported by the FFY 2009 data, which shows an increase in volume of 9.5%. ... For the purposes of the projections contained in this application, NCDI-Holly Springs has held the Wake County use rate constant, at 80.7, for the first three project years... .

Wake County- Projected Use Rate (unweighted volume)

Time Period	Unweighted MRI Volume	Wake County Population	Use Rate Per 1,000
FFY 2005	53,122	757,346	70.1
FFY 2006	55,692	793,401	70.1
FFY 2007	65,582	831,537	78.9
FFY 2008	65,808	866,438	75.9
FFY 2009	72,036	892,607	80.7
FFY 2010	74,269	920,307	80.7
FFY 2011	76,504	948,001	80.7
FFY 2012	78,739	975,696	80.7
FFY 2013	80,973	1,003,389	80.7
FFY 2014	83,209	1,031,086	80.7

By maintaining the same FFY 2009 use rate of 80.7 scans per thousand population, the Wake County compound annual growth rate for FFY 2010-2014 will decrease 2.3%.

This growth rate is considerably lower than Wake County's experience in the prior five year period from FFY 2005-FFY 2009 at 6.28%.

Step 3: Apply Wake County Use Rate to the Primary Service Area Population in Project volume [page 61]

NCDI-Holly Springs utilized the FY 2009 Wake County MRI use rate per 1,000 of 80.7 and applied it to the population projections for each census tract. The result was the projected unweighted MRI volume for each project year. As indicated below, the total estimated unweighted volume for the primary service area is expected to exceed 10,000 scans by the third year of operation.

Primary Service Area- Projected Unweighted Volume

Census Tract	CY 2012	CY 2013	CY 2014
532- Holly Springs	39,671	41,482	43,586
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	3,209	3,356	3,517
531.01-Fuquay Varina	19,202	20,046	20,926
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	1,550	1,618	1,689
531.03- Wake County	9,643	9,781	9,922
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	778	789	801
531.04- Wake County	11,547	11,892	12,247
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	932	960	988
534.04-Holly Springs/Apex	21,851	22,533	23,236
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	1,763	1,818	1,875
529-Wake County	15,769	16,106	16,450
Use Rate/100	80.7	80.7	80.7
Projected Unweighted MRI Volume	1,272	1,300	1,328
Total Projected Unweighted Volume for Primary Service Area	9,504	9,841	10,198

Step 4: Estimate Market Share Percentages for the Project [pages 62-63]

The following percent market share was used to project outpatient MRI volume for NCDI-Holly Springs. NCDI-Holly Springs proposes to reach the target market share in year three of operation. The following projections reflect the year to year rate of growth for market share in each census tract.

Census Tract	CY 2012	CY 2013	CY 2014
Census Tract 532	48%	53%	58%
Census Tract 531.01	30%	34%	38%
Census Tract 531.03	13%	15%	16%
Census Tract 531.04	30%	33%	36%
Census Tract 534.04	50%	53%	56%
Census Tract 529	12%	14%	16%

Market share assumptions were projected at the census tract level to address the proximity of the proposed outpatient imaging center to each population group and the proximity of other providers to the population. Market share assumptions were ramped up gradually over the projected timeframe. The total projected unweighted MRI volume at NCDI-Holly Springs as calculated below in Step 5, based upon these market share assumptions, is less than 6% of total unweighted MRI volume projected to be performed in Wake County in Project Year Three as reflected in Step 2 above. There are several factors that support the projected market share percentages, including but not limited to the following:

- *NCDI-Holly Springs Service Area population represents almost 12% of the total Wake County population.*
- *NCDI-Holly Spring's one fixed MRI scanner would represent 1/14, or 7% of the total fixed MRI scanners in Wake County.*
- *The estimated unweighted MRI volume for NCDI-Holly Springs represents less than 6% of total Wake County unweighted MRI volume as projected in Step 2.*
- *There are no existing fixed MRI scanners in the NCDI-Holly Springs Service Area.*
- *Novant Medical Group primary care physician offices with local access are planned for development in Holly Springs in and near the medical plaza where NCDI-Holly Springs and the proposed Novant Holly Springs Surgery Center will be located.*

Step 5: Apply Estimated Market Share Percentages to Projected Volume [page 64]

NCDI-Holly Springs- Projected Unweighted Volume by Census Tract

Census Tract	CY 2012	CY 2013	CY 2014
532- Holly Springs	3,209	3,356	3,517
Market Share Percentage	48%	53%	58%
Projected Unweighted MRI Volume for NCDI-Holly Springs	1,540	1,779	2,040
531.01-Fuquay Varina	1,550	1,618	1,689
Market Share Percentage	30%	34%	38%
Projected Unweighted MRI Volume for NCDI-Holly Springs	465	550	642
531.03- Wake County	778	789	801
Market Share Percentage	13%	15%	16%
Projected Unweighted MRI Volume for NCDI-Holly Springs	101	118	128
531.04- Wake County	932	960	988
Market Share Percentage	30%	33%	36%
Projected Unweighted MRI Volume for NCDI-Holly Springs	280	317	356
534.04-Holly Springs/Apex	1,763	1,818	1,875
Market Share Percentage	50%	53%	56%
Projected Unweighted MRI Volume for NCDI-Holly Springs	882	963	1,050
529-Wake County	1,272	1,300	1,328
Market Share Percentage	12%	14%	16%
Projected Unweighted MRI Volume for NCDI-Holly Springs	152	182	212
Total Projected Unweighted Volume for NCDI-Holly Springs (95% of total volume)	3,420	3,909	4,428

The chart above details the amount of unweighted MRI volume that NCDI-Holly Springs anticipates from the primary service area. ...

- *The Novant Medical Group of general surgeons is exploring a satellite office location in Holly Springs, near the NCDI-Holly Springs location.*
- *Novant Medical Group's positive reputation with local physicians and the steady growth of the Novant Medical Group-Triangle, which has grown from seven practice locations with 34 physicians and surgeons in 2008 to fourteen practice locations with 42 physicians and surgeons in 2010, including one new surgical practice.*
- *Letters of support from local providers indicating willingness to refer patients to the proposed facility which are included in Attachment 29.*
- *Congestion and traffic to Research Triangle Park, Cary, and downtown Raleigh continues to increase as population grows (Please see traffic/travel study in*

Attachment 30).

- *The proposed location of NCDI-Holly Springs adjacent to the new Western Wake Freeway will result in ease of access to the existing population in the defined zip code service area. The NCDI-Holly Springs site is strategically located in northern Holly Springs, between Highway 55 and Highway 55 Bypass, and is located within one mile of the proposed I-540 interchange with Highway 55 Bypass. (See discussion in response to Question III.1(a)).*
- *The new Western Wake Freeway will result in population growth in the defined zip code service area.*
- *Projected population growth in the defined NCDI-Holly Springs Service Area is projected to exceed 28% between 2009 and 2016.*

These qualitative and quantitative reasons all support the proposed market share assumptions reflected in the previous table for NCDI- Holly Springs.

Step 6: Other In-migration Assumption [page 65]

While not part of the defined NCDI-Holly Springs Service Area, NCDI-Holly Springs recognizes that patients from other areas may choose to travel to receive services at NCDI-Holly Springs as a result of convenience or patient choice.

As a result, NCDI-Holly Springs assumes that 5% of the total projected utilization in each of the project years will be from other areas or in-migration. The estimate of in-migration is consistent with the experience of other MedQuest facilities in North Carolina as to the fact that each facility generally sees patients from multiple counties and sometimes other states. ...

NCDI-Holly Springs Unweighted MRI Volume CY 2012 – CY 2014

Census Tract	Percent of Total	CY 2012	CY 2013	CY 2014
MRI Volume from NCDI-Holly Springs Service Area	95%	3,420	3,910	4,428
MRI Volume from Other Counties	5%	180	206	233
Total NCDI-Holly Springs Unweighted Volume	100%	3,600	4,116	4,661

Step 7: Convert Unweighted Procedures to Weighted Procedures [page 66]

After projecting the total number of unweighted MRI scans for the proposed fixed MRI scanner, NCDI- Holly Springs determined a reasonable contrast percentage to apply to the unweighted MRI volume. NCDI-Holly Springs reviewed the contrast percentages for the mobile service provided at NCDI-Cary during FY 2009, which was 19.5%. NCDI-Holly Springs also reviewed the contrast percentages for other MedQuest-managed facilities near Wake County. Considering these data sources, the 19.5 percentage for contrast is reasonable in light of experience of other MedQuest facilities

located in North Carolina near Wake County. The average for the four facilities was 23.1%.

Contrast Percentages for Other MedQuest Facilities

Facility Name	County	Total Scans	Contrast Scans	% Contrast
NCDI-Cary (Kings Medical Mobile)	Wake	388	76	19.5%
Durham Diagnostic Imaging	Durham	4,710*	1,622	34.4%
Triad Imaging	Guilford	5,663*	1,183	20.9%
Carolina Imaging	Cumberland	11,981*	2,087	17.45

**Includes fixed and mobile volumes.*

NCDI-Holly Springs also considered the contrast percentages performed by other freestanding fixed MRI centers in Wake County based on data from the Draft 2011 SMFP.

Contrast Percentages for Outpatient Fixed MRI Facilities in Wake County

Facility Name	Fixed Magnets	Total Scans	Contrast Scans	% Contrast
Raleigh MRI Center	1	4,394	1.991	45.3%
Raleigh MRI Center	1	4,152	1,841	44.3%
Raleigh Neurology Associates	1	6,431	2,216	34.5%
Raleigh Radiology	1	2,743	894	32.5%
Raleigh Radiology at Cedarhurst	1	6,869	1,529	22.6%
Average Contrast Percentage				35.8%

Source: Draft 2011 SMFP

...

Step 8: Apply Contrast Percentage to Determine Weighted Volume [page 67]"

NCDI- Holly Springs Unweighted & Weighted MRI Volume

Census Tracts		2012	2013	2014
532	Holly Springs	1,540	1,779	2,040
531.01	Fuquay Varina	465	550	642
531.03	Wake County	101	118	128
531.04	Wake County	280	317	356
534.04	Holly Springs/ Apex	882	963	1,050
529	Wake County	152	182	212
Primary Service Area Unweighted		3,420	3,909	4,428
Plus-In-migration @ 5%		180	206	233
Total Unweighted Volume		3,600	4,115	4,661
19.5% Contrast	Contrast Scans	702	802	909
Outpatient Contrast Adjustment (Contrast Scans x 0.4)		281	321	364
Total Weighted volume (Unweighted Volume + Contrast Adjustment)		3,881	4,436	5,025

...

NCDI-Holly Springs reviewed a variety of options and determined that the development of the proposed project is the most effective alternative to meet the current and future imaging needs of the residents of Wake County and in particular, the residents of southern Wake County, including the Town of Holly Springs. The proposed outpatient imaging center will be located in one of the most populous and fastest growing areas of Wake County and within one mile of the Holly Springs interchange with the Western Wake Freeway. The proposed project will result in greater convenience and expanded state-of-the-art imaging services in a comfortable, pleasant environment for residents of southern Wake County."

However, projected utilization is not based on reasonable and supported assumptions. In Step 4, the applicant makes the following assumptions regarding the projected market share for the proposed fixed MRI scanner:

"NCDI-Holly Springs Outpatient Imaging Center Projected Market Share: CY 2012 – CY 2014

Census Tract	CY 2012	CY 2013	CY 2014
Census Tract 532	48%	53%	58%
Census Tract 531.01	30%	34%	38%
Census Tract 531.03	13%	15%	16%
Census Tract 531.04	30%	33%	36%
Census Tract 534.04	50%	53%	56%
Census Tract 529	12%	14%	16%

However, the applicant does not adequately demonstrate that the assumptions shown in the table above are reasonable for the following reasons:

- In Attachment 29, the applicant provided letters from physicians which include estimates of the number of referrals to the proposed fixed MRI scanner. These estimates total only 117 referrals in PY1, 127 in PY2 and 134 in PY3. These estimated referrals are substantially below the levels needed to support the projected utilization in the first three operating years.

- In each project year, 15 of the estimated referrals are from a physician practice whose address is listed as Wake Forest which is located in the exact opposite corner of Wake County from the proposed facility. According to Google Maps, the distance between Holly Springs and Wake Forest is around 35-47 miles depending on the route taken. The applicant does not adequately demonstrate that it would be reasonable to assume that a physician practice located in Wake Forest would serve many residents of Holly Springs.

- In Step 4, the applicant states *"Novant Medical Group primary care physician offices with local access are planned for development in Holly Springs in and near the medical plaza."* In addition, the applicant states in Step 5 *"The Novant Medical Group of general surgeons is exploring a satellite office location in Holly Springs."* However, the applicant did not provide any details such as when the practices would open, how many physicians would be associated with these primary care physician offices or the projected number of referrals for MRI services. None of the reasons cited by the applicant on page 62 adequately support the projected market share assumptions. (See page 21 of the findings for the applicant's reasons.) For example, the applicant does not explain why its projected market share is positively correlated with the population of Holly Springs as a percentage of the total Wake County population. Even if it is, the population of Holly Springs represents only 12% of the total population of Wake County, yet the applicant projects a market share of 58% for one of the Holly Springs census tracts.

- In Step 5, the applicant applies the projected market share percentages from Step 4 to total projected unweighted MRI procedure volume by census tract. However, the applicant did not adequately demonstrate that its projected market share percentages are based on reasonable and supported assumptions. None of the reasons cited by the applicant on page 63 adequately support the projected market share assumptions. (See pages 22-23 of the findings for the applicant's reasons.)

- Therefore, projected utilization which is based on these market share assumptions is not based on reasonable and supported assumptions and is questionable.

Furthermore, the applicant projects that 2% of its MRI patients will be residents of Durham, Orange, Sampson, Nash, Craven, Wayne, Vance and Person counties. However, the applicant does not adequately demonstrate that it is reasonable to assume residents of those

counties would utilize the proposed MRI scanner in Holly Springs. Particularly since there are existing fixed and mobile MRI scanners in those counties, the facility does not yet exist and it would be located in Holly Springs, a community of less than 22,000 people.

In summary, the applicant did not adequately demonstrate the need the population to be served has for the proposed MRI scanner. Consequently, the application is nonconforming to this criterion.

Wake Radiology currently offers MRI services at its Garner office, an existing diagnostic center, through two different vendors, Alliance and Wake Radiology Diagnostic Imaging (one of the co-applicants). Wake Radiology plans to place the proposed fixed MRI scanner at its Garner office located at 300 Health Park Drive. The applicants state the mobile MRI scanner services would be discontinued at the Garner office.

Population to Be Served

In Section III.5(a), page 94, the applicants state "*The primary service area for the proposed fixed MRI scanner includes the following zip codes 27529, 27520, 27603, 27606, 27610, 27526, 27592, and 27545. The secondary service area for includes the remainder of Wake County not included by the primary service area zip codes. The rationale for establishing this service area is based on historical patient origin for MRI patients at WRGO.*"

In Section III.5(c), page 95, the applicant provides the current and projected patient origin for the first two years of operation following completion of the proposed project as shown in the table below:

Wake Radiology's Projected Patient Origin for MRI Services

County	Current Percent of Total	FY2012-FY2014 Percent of Total
Wake	60.5%	60.5%
Johnston	33.9%	33.9%
Harnett	5.7%	5.7%
Total	100.0%	100.0%

In Section III.5(d), pages 95-96, the applicants state "*The projected patient origin is consistent with WRGO's historical experience providing mobile MRI services. The applicants do not anticipate a significant change in patient origin as a result of providing fixed MRI services.*" The applicants adequately identified the population proposed to be served.

Need Analysis

In Section III.I, pages 59-75, the applicants state the need for the proposed fixed MRI scanner in Garner is based on the following:

> *"The proposed project is consistent with the unmet need, identified in the 2010 SMFP for one additional fixed MRI scanner in Wake County. To meet the identified need, WRS proposes to acquire and install a fixed MRI scanner to be placed at WRGO. The*

proposed fixed MRI scanner will be operated by WRDI. In evaluating the unmet need for the proposed MRI scanner, WRDI reviewed service area population growth trends, MRI growth in Wake County and at WRDI, and physician referral patterns. This need analysis is described below.

A. 2010 SMFP Need Methodology [pages 59-60 of the application]

Based on the 2010 SMFP Need Methodology, the State has determined a need for one additional fixed MRI scanner in Wake County in 2010.

In addition to the State's need determination, Wake Radiology recognizes that there are additional characteristics and data in Wake County that further support the need for an additional fixed MRI scanner in Wake County.

B. Population [pages 60-63 of the application]

The State-defined MRI scanner Service Area is Wake County. ... According to the NCOSBM, Wake County is expected to become the most populous county in North Carolina by 2013 and host more than one million residents. ... [T]he county population is expected to increase by approximately 110,779 people, or 12% percent during the next four years. ...

As described previously, the applicants propose to locate the fixed MRI scanner at the WRGO facility in Garner. Garner is a rapidly growing community within Wake County. ...

The primary service area for the proposed fixed MRI scanner includes the following zip codes: 27529, 27520, 27603, 27606, 27610, 27526, 27592 and 27545. The secondary service area includes the remainder of Wake County not included by the primary service area zip codes. ...

The rationale for establishing this service area is based on the historical patient origin for MRI patients at WRGO. Currently, 67.5% of WRGO patients originate from the service area. ...

Primary Service Area Projected Population

Zip Code	Area	2009	2014	10-14 CAGR
27520	Clayton	34,341	40,352	4.1%
27526	Fuquay Varina	38,825	47,185	5.0%
27529	Garner	40,905	47,748	3.9%
27545	Knightdale	18,380	20,107	2.3%
27592	Willow Spring	13,601	15,876	3.9%
27603	Raleigh	40,026	45,127	3.0%
27606	Raleigh	49,436	54,897	2.7%
27610	Raleigh	60,654	70,115	3.7%
Total Primary SA		296,168	341,407	3.6%

Source: Claritas

C. *MRI Utilization* [pages 63-67 of the application]

MRI utilization rates for Wake County continue to trend upward. ... Based on population data from NCOSBM and FY2009 MRI utilization from DHSR Planning Section, the Wake County MRI utilization rate was 80.7 procedures per 1,000 population in 2009. From 2004 to 2009, the Wake County MRI use rate experienced a compound annual growth rate of 3.7%.

Wake County MRI Use Rate per 1,000 Population FY 2004-FY2009

Year	Population	Unweighted MRI scans	MRI Procedure Rate (Per 1,000)
FY2004	725,334	48,815	67.3
FY2005	757,346	53,122	70.1
FY2006	793,401	55,692	70.2
FY2007	831,537	65,582	78.9
FY2008	866,438	65,892	76.0
FY2009	892,607	72,036	80.7
04-09 CAGR	4.2%	8.1%	3.7%

Source: NCOSBM, 2006-2010 SMFP, Draft 2011 SMFP data provided by SHCC Technology & Equipment Committee & DHSR Planning Section Totals may not foot due to rounding.

Wake County MRI Utilization

Wake County has also experienced substantial growth in MRI utilization.

Wake County Historical MRI Utilization FY2004 – FY2009

	Unweighted MRI Scans	Weighted MRI Scans
FY2004	48,815	57,537
FY2005	53,122	62,174
FY2006	55,692	65,936
FY2007	65,582	77,172
FY2008	65,892	77,428
FY2009	72,036	86,533
04-09 CAGR	8.1%	8.5%

Source: 2006-2010 SMFP, Draft 2011 SMFP data provided by SHCC Technology & Equipment Committee & DHSR Planning Section Totals may not foot due to rounding.

Unweighted MRI utilization in Wake County experienced a five-year compound annual growth rate of 8.1% from FY2004 to FY2009. Weighted MRI utilization increased 8.5% annually during the same time period. Based on historical growth rates combined with rapid population growth estimates, Wake County is likely to continue to utilize MRI services at increasing rates.

According to the 2010 SMFP, over 87% of MRI scans performed in Wake County are outpatient MRI procedures. Wake County inpatients and emergency patients are currently adequately served by six existing fixed MRI scanners located at Wake County hospitals. Thus, WRDI's proposal to establish a dedicated outpatient MRI scanner is an effective alternative.

Mobile MRI Utilization

...

FY2008 Mobile MRI Utilization Top North Carolina Counties

County	Fixed Equivalent Total	Unweighted Mobile Scans
Mecklenburg	5.18	16,478
Guilford	3.37	16,232
Wake	3.87	15,298
New Hanover	2.44	11,726
Forsyth	1.94	9,361

Source: 2010 SMFP

Wake County mobile MRI scanners average 3,953 unweighted scans per fixed equivalent magnet (4,218 weighted scans per fixed equivalent), which are both far above the 3,328 weighted scan State-defined mobile MRI capacity threshold. This demonstrates that mobile MRI scanners in Wake County are operating well above capacity. Furthermore, during the most recent fiscal year ending September 30, 2009, WRDI's mobile MRI scanner performed 3,560 weighted MRI procedures, which also exceeds the State-defined mobile MRI capacity threshold.

In summary, Wake County has historically experienced steady MRI growth, and, based on projected population growth rates, the demand for MRI services will continue to increase. Furthermore, given that the majority of MRI scans are performed on an outpatient basis, Wake County residents would benefit most from a facility dedicated to providing outpatient MRI services. Thus, to meet the growing demand for outpatient MRI services in Wake County, the applicants propose to install a new fixed MRI scanner at the WRGO facility in Garner.

D. *Geographic Need* [pages 68-75 of the application]

...

There are thirteen existing fixed MRI scanners in the Wake County MRI Service Area. Ten fixed MRI scanners are located in Raleigh, and three fixed MRI scanners are located in Cary. There are currently no fixed MRI scanners located in Garner. ...

WRDI's proposed location at 300 Health Park Drive in Garner is more than 10 miles from the two fixed MRI scanners located at WakeMed Raleigh Hospital, 13 miles from the fixed scanner at Duke Raleigh Hospital, 14 miles from two fixed MRI scanners at the Raleigh MRI location on Merton Drive, 14 miles from one fixed MRI

scanner at Raleigh Radiology Cedarhurst, 18 miles from the fixed MRI scanner at WakeMed Cary Hospital, and 20 miles from the fixed MRI scanner at Rex Healthcare of Cary.

According to North Carolina Office of State Budget & Management (NCOSBM) population estimates, the communities in southeastern Wake County (Garner and the surrounding area) have experienced significant population growth in recent years.

Southeast Wake County
2008 Municipal Estimates by Municipality

Municipality	2000	2008	% Growth
Garner	17,787	26,109	46.8%
Holly Springs	9,192	20,631	124.4%
Knightdale	5,958	10,967	84.1%
Fuquay-Varina	7,898	16,054	103.3%
Wendell	4,247	5,796	36.5%
Wake County	633,516	866,438	36.85
North Carolina	8,079,712	9,247,173	14.4%

Source: NC Office of State Budget & Management

... Municipal population projections are not available on the NCOSBM website; however, WRDI obtained the following population projections from Claritas which demonstrate continued growth for the municipalities in southeast Wake County during the next five years. ...

Southeast Wake County
Claritas Population Projections by Municipality

	2009	2014	% Growth
Fuquay-Varina town	14,267	17,653	23.7%
Garner town	24,023	27,666	15.2%
Holly Springs town	18,063	22,763	26.0%
Knightdale town	7,305	8,181	12.0%
Wendell town	4,776	5,176	8.4%

Source: Claritas

... Out of the municipalities listed, Garner has the lowest per capita income currently and also five years from now, at $23,892 and $25,159 respectively. A lower per capita income average traditionally results in difficulties in obtaining equal access to health services. Therefore, the proposed fixed MRI scanner at WRGO will ensure access to MRI services for underserved populations.

Municipalities in Wake County
Per Capita Income 2009- 2014

Municipality	2009 Per Capita Income	2014 Per Capita Income
Cary	$39,069	$42,009
Morrisville	$38,343	$41,121
Apex	$36,649	$39,941
Wake Forest	$27,800	$29,893
Raleigh	$27,629	$29,219
Garner	$23,892	$25,159

...

Fixed & Mobile MRI Access

... Wake County hosts several mobile MRI sites, including WRGO. Based on FY2008 data reported in the 2010 SMFP, Wake County has the third highest utilization of mobile MRI services in North Carolina, behind Mecklenburg and Guilford counties. Despite numerous mobile MRI scanners located in Wake County, Garner remains underserved with regard to MRI access. ... The applicants then determined the number of either fixed or mobile MRI sites within a five-mile radius of each municipality.

...

The following table provides Claritas population estimates for Wake County municipalities including the number of fixed and/ or mobile MRI host sites within a 5-mile radius of each municipality.

	2009 Population	Fixed & Mobile Magnets <5 miles	Ratio of pop/scanner
Raleigh city	371,092	13	28,546
Garner town	24,023	1	24,023
Cary town	126,832	11	11,530
Wake Forest town	25,307	3	8,436
Knightdale town	7,305	1	7,305
Apex town	30,480	6	5,080
Morrisville town	10,877	3	3,626
Holly Springs town	18,063	0	—
Fuquay-Varina town	14,267	0	—
Wendell town	4,776	0	—
Zebulon town	4,342	0	—

Source: Claritas, 2010 SMFP

Based on the current locations of fixed and mobile MRI scanners, Garner is significantly underserved by MRI scanners compared to other municipalities in Wake County. The Town of Wake Forest is similar in population to the Town of Garner; however, Wake Forest residents currently have access to mobile MRI scanners at three different host sites. Garner residents only have access to mobile MRI services

at WRGO. Furthermore, Morrisville has less than half the population of Garner yet still has access to mobile MRI scanners at three different host sites.

In summary, Garner is currently underserved with regard to MRI services. WRGO is an established MRI provider in the service area that has long-standing relationships with local referring physicians. Thus, the proposed fixed MRI scanner at WRGO will greatly increase geographic access to fixed MRI services in Wake County for a rapidly growing market.

E. Physician Referrals [page 75 of the application]

Radiologists do not refer patients for MRI scans. Rather, local physicians in Wake County and surrounding communities are the primary source of referrals to the existing and proposed MRI services at WRGO. WRDI is a well-established and trusted local provider of MRI services in Wake County. As such, WRDI has long-standing relationships with local referring physicians. In fact, the applicants have received over 175 letters of support from local physicians who refer patients to WRGO. Based on the referral estimates provided in these letters of support, local physicians have indicated their intent to refer over 4,300 MRI patients to the proposed fixed MRI scanner located at WRGO. This is further evidence of the need for the proposed service at WRGO's facility in Garner. The proposed fixed MRI scanner at will be available to all physicians and their patients, regardless of the patient's ability to pay. Please refer to Exhibit 18 for letters of support for the proposed fixed MRI scanner."

Historical and Projected Utilization

In Section IV.1, pages 99-101, the applicants provide historical and projected utilization for the existing mobile MRI services and the proposed fixed MRI scanner at WRGO through the first three project years, as illustrated in the table below.

	FY2008	FY2009	FY2010 - Interim (Oct-Sept)	FY2011- Interim (Oct-Sept)	FY2012 (Oct-Sept)	FY2013 (Oct-Sept)	FY2014 (Oct-Sept)
# of MRI Scanners							
Fixed					1	1	1
Mobile	1	1	1	1			
#of Procedures	2,483	2,323	2,417	2,515	3,298	3,851	4,444
#of Weighted Procedures	2,723	2,585	2,690	2,798	3,670	4,285	4,945
Percentage Change in Weighted Procedures	-na-	(-5.1%)	4.1%	4.1%	31.2%	16.75%	15.4%

As shown in the table above, in FY2009, 2,585 weighted MRI procedures were performed on the mobile MRI scanners at WRGO, a 5.1% decrease from the year before. In the third project year, the applicants project the proposed fixed MRI scanner will perform 4,945 weighted MRI procedures, which exceeds the 4,805 required by 10A NCAC 14C .2703(b)(3). To reach that volume, Wake Radiology assumes volume at WRGO will increase 4.1% each year before the fixed MRI scanner is operational. Between FY 2011 and FY 2012 (PY1), Wake Radiology assumes volume will increase 31.2%. Between PY1 and PY2, volume is projected to increase another 16.75%. Between PY2 and PY3, volume is projected to increase another 15.4%. All together, Wake Radiology projects volume will increase 91.3% between FY 2009 and PY3 (FY 2014) (a 5-year period) [4,945 – 2,585 = 2,360; 2,360/2,585 = 0.913]. This, despite a 5.1% decrease between FY 2008 and FY 2009 at WRGO and decreases at Raleigh MRI, which is owned by Wake Radiology and has two existing fixed MRI scanners. See discussion below. The applicants do not adequately explain why utilization is expected to now start increasing.

In Section III.1, pages 76-83, the applicants provide the assumptions and methodology used to project utilization at the proposed fixed MRI scanner at WRGO, as follows:

"Specific Methodology for Projecting MRI Utilization at WRGO

The following provides the specific methodology used to project MRI utilization for the proposed fixed MRI scanner that will be located at WRGO.

Step 1: Identify Historical Wake County MRI Utilization

The following table provides historical MRI utilization for Wake County.

Wake County
Historical MRI Scans
FY2004 - FY2009

Year	Unweighted MRI Scans
FY2004	48,815
FY2005	53,122
FY2006	55,692
FY2007	65,582
FY2008	65,892
FY2009	72,036
04-09 CAGR	8.1%

Source: State Medical Facilities Plan (2006-2010), Draft 2011 SMFP data provided by SHCC Technology & Equipment Committee & DHSR Planning Section. Totals may not foot due to rounding.

The number of unweighted MRI scans performed in Wake County experienced a five-year compound annual growth rate of 8.1% from FY2004 to FY2009. Despite recent economic distress (experienced at its height during FY2008), the number of MRI scans in Wake County have continued to increase. While most counties saw a decrease in MRI

scans during FY2008, the total number of MRI scans performed in Wake County actually increased. As a sign of economic recovery, Wake County MRI procedures increased 9.3% during FY2009 compared to the previous year.

Step 2: Project Future Wake County MRI Utilization

To project Wake County MRI utilization from FY2010 to FY2014, the applicants utilized one-half of the FY2004-FY2009 compound annual growth rate (8.1% ÷2= 4.0%) for MRI scans performed in Wake County.

Wake County Projected MRI Scans
FY2010-FY2014

Year	Unweighted MRI Scans
FY2010	74,951
FY2011	77,984
FY2012	81,140
FY2013	84,423
FY2014	87,840

Totals may not foot due to rounding.

The projected annual growth rate of 4.0% is reasonable and conservative based on the historical utilization for MRI services in Wake County. As stated previously, the most recent five-year compound annual growth rate for Wake County was 8.1% from FY2004 to FY2009, and the most recent one-year annual increase was 9.3% from FY2008 to FY2009.

Step 3: Determine Reasonable MRI Market Share Assumptions

To project reasonable market share assumptions for the proposed Garner fixed MRI scanner, Wake Radiology first determined WRGO's current market share in Wake County. During the most recent fiscal year ending September 30, 2009 (FY2009), WRGO performed a total 2,323 unweighted mobile MRI scans on the WRDI mobile MRI scanner and the Alliance MRI scanner combined. Based on the total number of MRI scans performed in Wake County during FY2009, WRGO's current market share is approximately 3.2%.

Wake Radiology Garner Office
FY2009 MRI Market Share
(Based on Mobile MRI Utilization)

Wake County MRI Scans	WRGO Mobile MRI Scans	FY2009 Market Share
72,036	2,323	3.2%

Source: 2011 SMFP data provided by SHCC Technology & Equipment Committee & DHSR Planning Section, Wake Radiology Internal Data. Totals may not foot due to rounding.

To remain conservative, the applicants project WRGO's Wake County market share to remain constant until the first year of the proposed project. Upon implementation of the

proposed project, the applicants project WRGO's market share to increase to 4.0% during Project Year 1, 4.5% during Project Year 2 and 5.0% during Project Year 3.

Wake Radiology Garner Office
Projected MRI Market Share

			PY1	PY2	PY3
	2010	2011	2012	2013	2014
MRI Market Share	3.2%	3.2%	4.0%	4.5%	5.0%

The projected MRI market shares are reasonable and conservative. First, WRGO's MRI market share is projected to remain constant until the first year of the proposed project. WRGO has provided mobile MRI services at its facility in Garner for six years, and has long-standing, established relationships with local referring physicians. Thus, it is reasonable to project that WRGO's MRI market share will remain constant until FY2012. The applicants project modest market share increases during the first three project years based on the written commitment of local physicians to refer patients to the proposed fixed MRI scanner in Garner. Based on the referral estimates provided in these letters of support, local physicians have indicated their intent to refer over 4,300 MRI patients to the proposed fixed MRI scanner located at WRGO. This is much greater compared to WRGO's most recent mobile MRI utilization of 2,323 unweighted MRI scans during FY2009. Additionally, the projected market shares are supported by the following factors:

* *The proposed project will increase MRI access at WRGO from 40 hours to 66 hours each week, an increase in availability of 65%.*
* *WRS and WRDI will establish the first freestanding, dedicated outpatient 1.5T fixed MRI scanner owned by local physicians in Garner.*
* *As described in Section II, the proposed project will increase access to MRI services for obese and claustrophobic patients.*
* *WRS and WRDI have received over 175 letters of support representing indicating their intent to refer at over 4,300 patients to the proposed fixed MRI scanner. Please refer to Exhibit 18.*
* *WRGO will establish a new, free-standing non-hospital based fixed MRI service with a lower charge structure compared to existing hospital-based MRI services in Wake County. Currently, the hospital-based MRI scanners at WakeMed are the closest in proximity to Garner-area residents.*

Step 4: Project MRI Scans at WRGO

The applicants applied market share projections in Project Years 1 through 3 to the projected Wake County MRI utilization.

WRGO Projected Unweighted MRI Utilization
Proposed Fixed MRI Scanner

Project Year	Projected Wake County MRI Scans	WRGO Outpatient Market Share	Projected WRGO MRI Scans
FY2012	81,140	4.0%	3,246
FY2013	84,423	4.5%	3,799
FY2014	87,840	5.0%	4,392

Totals may not foot due to rounding.

If awarded a fixed MRI scanner, the applicants have offered to partner with Project Access, a program of the Wake County Medical Society, to provide one free MRI scan each week to local patients who are uninsured or underinsured. The agreement will provide 52 charitable scans each year in the local community. Please refer to Exhibit 8 for correspondence between Project Access and WRS/WRDI regarding this agreement. These are patients who otherwise would not receive MRI services; thus, the projected 52 scans each year are in addition to the projected MRI utilization based on market share. Therefore, the applicants project the following MRI procedures in the first three years of the proposed project.

WRGO Projected MRI Utilization
Proposed Fixed MRI Scanner

	2012	2013	2014
Unweighted MRI Scans	3,246	3,799	4,392
MRI Scans Committed to Project Access	52	52	52
Total Unweighted MRI Scans	3,298	3,851	4,444
Weighted MRI scans	3,670	4,285	4,945

Totals may not foot due to rounding.

Utilization for the proposed fixed MRI scanner is projected to be 4,444 unweighted MRI procedures during the third year of the proposed project (FY2014). The applicants project weighted MRI procedures based on the historical contrast utilization at WRGO. Based on FY2009 data, WRGO's MRI procedure mix was 28.2% contrast and 71.8% non-contrast[15].

[15- Based on FY2009 utilization provided on both WRDI's mobile MRI scanner and a mobile MRI contract with Alliance Imaging, WRGO provided 655 outpatient MRI procedures with contrast and 1,668 without contrast for a total 2,323 mobile MRI procedures.]

Physician Referrals

As described previously, physicians are the primary source of referrals to the proposed fixed MRI service. WRS and WRDI received over 175 letters of support from local physicians who refer patient for MRI services in Wake County. ...

The proposed fixed MRI scanner at WRGO will be available to all physicians and their patients, regardless of the patient's ability to pay. Please refer to Exhibit 18 for letters of support from physicians indicating their intent to refer to the proposed fixed MRI scanner.

In summary, WRGO has provided mobile MRI services to the residents of Wake County and surrounding communities for six years. Currently, a mobile MRI scanner is on-site five days each week (Monday-Friday 8:00am-5:00pm). WRDI's proposed fixed MRI scanner will:

> *expand MRI access at WRGO to six days (66 hours) week,*
> *improve physical access to MRI services for patients,*
> *reduce the cost of providing MRI services at WRDI,*
> *increase access to uninsured and underinsured patients via agreement with Project Access of Wake County,*
> *insure continuing access to Medicare and Medicaid patients, and*
> *increase access to obese and claustrophobic patients."*

However, projected utilization of the proposed fixed MRI scanner at WRGO is not based on reasonable and supported assumptions. In Step 4 of the methodology, the applicants project their market share will increase from the current 3.2% of all unweighted MRI procedures performed in Wake County to 4.0%, 4.5% and 5.0%, respectfully. As illustrated in the table below, between FY2008 and FY2009, the number of unweighted MRI procedures performed at WRGO decreased by 5.1%.

	FY2008- Actual (Oct-Sept)	FY2009- Actual (Oct-Sept)
#of MRI Procedures	2,483	2,323
#of Weighted MRI Procedures	2,723	2,585
Percentage Increase (Decrease) in Weighted Procedures	-na-	(5.1%)

The decrease in utilization at WRGO between FY2008 and FY2009 is in contrast to a 9.3% increase in the total number of unweighted MRI procedures performed in Wake County at all locations, including WRGO, between FY2008 and FY2009. The applicants do not adequately explain this decrease in their application.

Furthermore, the applicants do not adequately explain decreases in utilization at Raleigh MRI. The table below illustrates historical and projected utilization of the two fixed MRI scanners at Raleigh MRI.

Raleigh Fixed MRI utilization (Historical and Projected)

	FY2005	FY2006	FY2007	FY2008	FY2009	FY 2010 Projected-Interim	FY 2011 Projected-Interim	PY1 FY 2012	PY2 FY 2013	PY3 FY 2014
Unweighted	11,852	10,576	10,009	9,842	8,546	8,731	8,919	9,112	9,309	9,511
Weighted	13,204	11,837	11,308	11,272	10,078	10,297	10,519	10,747	10,979	11,216
% change in weighted	-na-	<11.55%>	<4.7%>	<0.32%>	<11.85%>	2.2%	2.2%	2.2%	2.2%	2.2%

As shown above, for each year from FY2005 to FY2009, the number of MRI procedures performed on the two fixed MRI scanners at Raleigh MRI has decreased. The applicants do not provide an explanation for this other than to state that the economy was difficult in FY2008. Furthermore, the applicants do not adequately document that it is reasonable to assume volume at Raleigh MRI will increase except to state in Section II.8, page 35, "*During FY2009, WRDI performed 8,546 unweighted MRI scans on the two fixed MRI scanners located at Raleigh MRI. To project MRI utilization at Raleigh MRI through FY2014, WRDI conservatively applied three-fourths of the projected population growth rate for Wake County (2.9% x .75 = 2.2%) to its most recent historical MRI utilization.*" The applicants tied MRI growth at Raleigh MRI to population growth. However, as shown in Section III.1, page 64, the population of Wake County increased at a compound annual growth rate ("CAGR") of 4.2% from FY2004 to FY2009, the same years during which utilization of the two fixed MRI scanners at Raleigh MRI declined every year.

In FY2008, the applicants "market share" of the total number of unweighted MRI procedures performed anywhere in Wake County was 3.8% (2,483 procedures/ 65,892 Wake County procedures = .03768 or 3.8%). In contrast, in FY2009, the applicants "market share" of the total number of unweighted MRI procedures performed anywhere in Wake County declined from 3.8% to 3.2% (2,323 procedures/ 72,036 Wake County procedures = 0.03224 or 3.2%). By projecting a 5.0% "market share" in FY2014 at WRGO, the applicants project a 56.25% increase in "market share" in a five (5) year period (5.0% / 3.2% = 1.5625 or 56.25%). In support of this projected growth, in Exhibit 18, the applicants submitted over 175 letters of support from "*local physicians who refer patients to WRGO. Based on the referral estimates provided in these letters of support, local physicians have indicated their intent to refer over 4,300 MRI patients to the proposed fixed MRI scanner located at WRGO.*" [See page 75 of application.] If these physicians were to refer 4,300 patients to WRGO for an MRI procedure, it would be an 85% increase in the number of referrals (4300 / 2323 = 1.851 or 85.1%). However, the applicants do not adequately explain what will change to cause these physicians to increase their referrals to WRGO by 85.1%.

In the interim years before the proposed fixed MRI scanner is operational, the applicants project volume on the mobile MRI scanners at WRGO will increase 4.1% annually. However, the applicants do not adequately demonstrate that this assumption is reasonable and supported given the 5.1% decrease at WRGO between FY2008 and FY2009. The applicants do not adequately explain what will change to cause volume to increase before the proposed fixed MRI scanner would be operational.

Between FY 2011 and FY2012 (Year 1), the applicants project the number of weighted MRI procedures performed at WRGO will increase 31.2%. The applicants state what would be different at WRGO between FY2011 and FY2012 (Year 1) to explain the projected increase in the number of weighted MRI procedures to be performed at WRGO between FY2011 and Year 1. That is, WRGO's hours of operation will increase 65% once the proposed fixed MRI scanner begins operating [66-40 = 26; 26/40 = 0.65].

Between FY 2012 and FY2013 (Years 1 and 2) the applicants project the number of weighted MRI procedures performed at WRGO will increase 16.75% Furthermore, between FY2013 and FY2014 (Years 2 and 3) the applicants project the number of weighted MRI procedures performed at WRGO will increase 15.4%. However, the applicants do not adequately demonstrate that it is reasonable to assume that utilization will increase 16.75% at WRGO between Years 1 and 2 and 15.4% between Years 2 and 3 given the 5.1% decrease in the number of weighted MRI procedures performed at WRGO between FY 2008 and FY2009. Furthermore, according to the applicants (see Section III.1, page 66), between FY2004 and FY 2009, the CAGR for unweighted MRI procedures performed in Wake County was only 8.1%, roughly half of the percentage increase projected by the applicants between Years 1 and 2 and Years 2 and 3.

Moreover, the applicants do not state what would be different at WRGO between Years 1 and 2 or Years 2 and 3. Physician referrals for an MRI procedure have decreased recently. Thus, the physician's referral practices would have to change somehow if the number of referrals is going to increase 16.75% between Years 1 and 2 and 15.4% between Years 2 and 3. The applicants do not adequately explain how the physician's referral practices would change such that referrals would increase 16.75% and 15.4% respectively or provide documentation to support such an assumption.

Furthermore, in support of the proposed fixed MRI scanner the applicants state that it would be able to accommodate obese and claustrophobic patients. However, there is nothing in the application or the physician letters of support regarding the number of obese or claustrophobic patients who would normally be referred to WRGO but instead are being referred elsewhere. In addition, the applicants do not provide projected estimates of the number of MRI procedures which would be performed at WRGO on the proposed fixed MRI scanner on obese or claustrophobic patients. Neither the applicants nor the physicians state that the proposed fixed MRI scanner is capable of performing certain types of procedures which the mobile scanners are not capable of performing.

In addition, the applicants state on page 93 of the application that 33.1% of WRGO's 2009 MRI patients originated from Johnston County. Based on 2,323 unweighted MRI procedures that means that, in 2009, approximately 769 patients originated from Johnston County (2,323 x 0.331% = 768.91). On page 95, the applicants project that during FY2012-2014, 33.9% of its patients would originate from Johnston County. Based on the applicants estimate of 4,444 unweighted MRI procedures during FY2014 that means the applicants project approximately 1,507 patients will be residents of Johnston County. [4,444 x 33.9% = 1,506.5] Therefore, the applicants are projecting a 95.9% increase in the number of residents of Johnston County who will have an MRI procedure at WRGO (1,506.5 / 768.9 = 1.9592 or 95.9%). Of the 175

letters from physicians in Exhibit 18, 14 are from physicians located in Johnston County projecting a total of 615 referrals. The two main travel corridors from Johnston County to WRGO (the site of the proposed fixed MRI scanner) are I-40 and US 70. Johnston MRI, LLC was approved for and developed a new fixed MRI scanner which was operational as of September 2009 located in Clayton, adjacent to US 70 and located between the bulk of Johnston County and WRGO.. Pinnacle Health Services of North Carolina, LLC d/b/a Raleigh Radiology at Cedarhurst ("Pinnacle") received CON approval to acquire a 1.5 Tesla open mobile MRI scanner to serve a host site at 300 Guy Road, Clayton. [Project ID #J-8268-08. Under appeal by Wake Radiology.] The host site is adjacent to US-70 and close to I-40. Pinnacle described the approved open mobile MRI scanner as follows

> *"Siemens mobile MRI systems are designed and equipped to provide the same diagnostic performance as that of the fixed Magnetom systems delivering leading applications, superb patient comfort, and efficient workflow to any place.*
>
> *The proposed Siemens Magnetom Espree's unique Open Bore design can accommodate more types of patients than other 1.5T systems on the market today, in particular the growing population of obese patients. The power of 1.5T combined with "TIM" technology boosts signal-to-noise, which is necessary to adequately image obese patients.*
>
> *The proposed MRI system is also designed for an improved patient experience for claustrophobic patients."* See page 8 of the Findings for Project ID #J-8268-08.

The type of fixed MRI scanner that Wake Radiology is proposing to acquire is a Siemens 1.5T Magnetom Avanto MRI System equipped with "TIM" (Total Imaging Matrix).

The applicants do not adequately demonstrate that it is reasonable to assume a 95.9% increase in the number of Johnston County patients who will utilize WRGO once it has a fixed MRI scanner given the development of one new fixed MRI scanner and the approval of a new Open Bore Mobile MRI Scanner designed to accommodate both obese and claustrophobic patients at an existing host site in the same general area.

The applicants will have a total of three existing, approved and proposed fixed MRI scanners by the third operating year of this project. In Section II.8, page 34, the applicants project the average annual utilization of the existing, approved and proposed fixed MRI scanners (2 existing at Raleigh MRI and 1 proposed at WRGO) will be 4,896 weighted MRI procedures (4,945 on proposed fixed MRI scanner at WRGO + 9,744 on the two existing MRI scanners at Raleigh MRI = 14,689/3 MRI scanners = 4,896) in the third operating year.

However, the applicants did not adequately demonstrate that the two fixed MRI scanners at Raleigh MRI would reasonably perform 9,744 weighted MRI procedures in the third project year. The applicants used the following assumptions and methodology to project utilization of the two existing fixed MRI scanners at Raleigh MRI and the existing mobile MRI scanner (owned by WRS and operated by WRDI):

First, the applicants started with the actual number of MRI procedures performed in FY2009 on the two fixed MRI scanners located at Raleigh MRI and projected a 2.2% increase in unweighted MRI procedures for each year from FY2010 through FY2014. (See Section II.8, pages 35-36). The table below illustrates the historical and projected unweighted and weighted MRI procedures for the two fixed MRI scanners at Raleigh MRI.

Raleigh MRI Projected Utilization

	FY2009	FY 2010 Projected-Interim	FY 2011 Projected-Interim	PY1 FY 2012	PY2 FY 2013	PY3 FY 2014
Unweighted MRI Procedures	8,546	8,731	8,919	9,112	9,309	9,511
Weighted MRI Procedures	10,078	10,297	10,519	10,747	10,979	11,216
% change in weighted	<11.85%>.	2.2%	2.2%	2.2%	2.2%	2.2%

Second, the applicants then stated that WRDI would locate its mobile MRI scanner at Raleigh MRI for three days per week and assumed 1,248 of those unweighted MRI procedures would be performed on the mobile, as illustrated in the table below. (See Section II.8, pages 36-37.)

Raleigh MRI Projected Utilization

	FY2012	FY2013	FY2014
Fixed MRI procedures	7,864	8,061	8,263
Mobile MRI procedures	1,248	1,248	1,248
Total unweighted MRI procedures	9,112	9,309	9,511

Third, the applicants then converted the unweighted fixed MRI procedures not allocated to the mobile MRI scanner to weighted MRI procedures as shown in the table below.

	FY2012	FY2013	FY2014
Unweighted MRI procedures	7,864	8,061	8,263
Weighted MRI procedures	9,275	9,507	9,744

The applicants assume the two existing fixed MRI scanners at Raleigh MRI will perform 9,744 weighted MRI procedures in Year 3, which is an average of 4,872 weighted MRI procedures per scanner. [9,744/ 2 = 4,872 weighted MRI procedures per MRI scanner]. As noted above, the proposed fixed MRI scanner at WRGO is projected to perform 4,945 weighted MRI procedures in year 3. Thus, the three fixed MRI scanners (2 at Raleigh MRI and one proposed at WRGO) are projected to average 4,896 weighted MRI procedures.

However, Wake Radiology did not adequately demonstrate that projected utilization of the proposed fixed MRI scanner at WRGO is based on reasonable and supported assumptions. See discussion above.

Furthermore, the applicants did not adequately demonstrate that projected utilization of the two existing fixed MRI scanners at Raleigh MRI is based on reasonable and supported assumptions. See discussion above.

In Section II.8, page 47, the applicants state that WRS owns and WRDI operates one mobile MRI scanner in the MRI service area (Wake County). In Section II.8, pages 39-41, the applicants project the mobile MRI scanner will perform 3,484 weighted procedures in Year 3. In Section II.8, pages 39-41, the applicants provide *"projected unweighted and weighted MRI utilization by site for WRDI's existing mobile MRI scanner. For information purposes, mobile MRI services are currently offered at each of the sites identified in the following tables."* See the following tables.

Raleigh MRI- Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2007	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures	350	432	19	-na-	-na-	1,248	1,248	1,248
Weighted MRI Procedures						1,406	1,406	1,406

Wake Radiology Northwest Raleigh Office
Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures	-na-	20*	—	—	728	832	936
Weighted MRI Procedures	-na-				815	932	1,048

*9/1/09 – 9/30/09 only. Total of 36 hours.

Wake Radiology Wake Forest Office
Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures					728	832	936
Weighted MRI Procedures					801	915	1,030

**No data for 2008-2011.*

The table below illustrates the total projected unweighted and weighted MRI procedures for FY2012-FY2014 for all three of the listed host sites.

Total- All Three Projected Host Sites
Projected Mobile MRI Procedures FY2012-FY2014

	2012	2013	2014
Total Unweighted MRI Procedures	2,704	2,912	3,120
Total Weighted MRI Procedures	3,022	3,253	3,484

However, projected utilization of the mobile MRI scanner at Raleigh MRI is based on projected utilization of the fixed MRI scanners at Raleigh MRI. Projected utilization of the fixed MRI scanners at Raleigh MRI is not based on reasonable and supported assumptions. See discussion in 10A NCAC 14C .2703(b)(3). Therefore, projected utilization of the mobile MRI scanner is also questionable.

Furthermore, Wake Radiology did not provide the methodology and assumptions used to project utilization of the mobile MRI scanner at two other host sites: the Northwest Raleigh Office and the Wake Forest Office other than to state *"For information purposes, mobile MRI services are currently offered at each of the sites identified in the following tables."* [See Section II.8, pages 39-41.] In Section II.8, page 47, the applicants did state that for the 12-month period ending September 30, 2009, 20 unweighted/ 22 weighted MRI procedures were performed at the Northwest Raleigh Office. Wake Radiology did not supply any year-to-date information as to the number of MRI procedures (either unweighted or weighted) performed at either the Northwest Raleigh Office or the Wake Forest Office after September 30, 2009. This application was submitted on June 15, 2010.

In summary, the applicants did not adequately demonstrate that projected utilization of the proposed fixed MRI scanner at WRGO, the two existing fixed MRI scanners at Raleigh MRI or the existing mobile MRI scanner owned by Wake Radiology is based on reasonable and supported assumptions. Consequently, the applicants did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner at WRGO. 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.

NA – All Applications

(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.

C –Duke Raleigh
NC- NCDI- Holly Springs
NC- Wake Radiology

Duke Raleigh In Section III.3, pages 30-31, the applicant describes the alternatives it considered. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and 10A NCAC 14C .2700 for discussion. Therefore, the applicant adequately demonstrated that the proposal is its least costly or most effective alternative and the application is conforming to this criterion.

NCDI- Holly Springs In Section III.3, pages 75-76, the applicant describes the alternatives it considered. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (18a) and 10A NCAC 14C .2700 for discussion. 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.

Wake Radiology In Section III.3, pages 89-92, the applicants describe the alternatives they considered. However, the application is not conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (18a) and 10A NCAC 14C .2700 for discussion. Therefore, the applicants did not adequately demonstrate that the proposal is their 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.

C – Duke Raleigh
NC – NCDI-Holly Springs
NC- Wake Radiology

Duke Raleigh In Section VIII, page 65, the applicant states that the total capital cost of the proposed project is $4,972,700, which includes:

Site Costs	$ 292,100
Cost of Materials	$1,122,000
Cost of Labor	$ 918,000
Fixed Equipment	$2,049,000
Movable Equipment	$ 79,600
Furniture	$ 13,600
Architect & Engineering	$ 345,000
Independent Testing	$ 12,900
Other (Contingency)	$ 140,500
Total	$4,972,700

In Section IX.1, page 70, the applicant states that there will be no startup expenses or initial operating expenses. In Section VIII.3, page 66, and in Section VIII.8, page 67, the applicant states that the capital costs of the proposed project will be financed through the accumulated reserves of Duke University Health System.

Exhibit VIII.6 contains a copy of a letter dated May 13, 2010 from the Senior Vice President, Chief Financial Officer and Treasurer of the Duke University Health System, which states:

> *"This letter is to certify that Duke University Health System has as much as $6 million in accumulated reserves to fund the acquisition of a second fixed MRI scanner and the new construction and renovations essential to its installation and efficient operation."*

Exhibit VIII.9 contains a copy of the audited financial statements for Duke University Health System, Inc. and Affiliates for the year ending June 30, 2009. As of June 30, 2009, Duke

University Health System, Inc. and Affiliates had cash and cash equivalents of $98,925,000, unrestricted net assets of $1,348,045,000 and total net assets of $1,392,169,000. The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The following table illustrates projected revenues, expenses and average charge per unweighted MRI procedure as reported by the applicant in Form C and Form D. Note: the charges include only the technical component.

Duke Raleigh- MRI Service Component

	Year 1- (7/1/11 -6/30/12)	Year 2- (7/1/12 – 6/30/13)	Year 3- (7/1/13 – 6/30/14)
Projected # of Unweighted Procedures	6,654	7,269	8,034
Projected Average Charge (Gross Patient Revenue / Projected # of Procedures)	$2,576.30	$2,730.95	$2,894.95
Gross Patient Revenue	$17,142,718	$19,851,292	$23,258,028
Deductions from Gross Patient Revenue	$11,681,400	$13,755,627	$16,334,823
Net Patient Revenue	$5,461,317	$6,095,665	$6,923,205
Total Expenses	$1,760,967	$1,988,733	$2,071,847
Net Income	$3,700,351	$4,106,892	$4,851,358

As illustrated in the table above, the applicant projects that net revenues for the MRI service component will exceed expenses during each of the first three operating years. The following table illustrates projected revenues and expenses for Duke University Health System as reported by the applicant in Form B.

Duke University Health System
Revenues and Expenses for Entire Health System

*Note: All $ are in 000's.	Year 1- (7/1/11 -6/30/12)	Year 2- (7/1/12 – 6/30/13)	Year 3- (7/1/13 – 6/30/14)
Total Operating Revenue	$2,333,141	$2,483,205	$2,726,652
Total Operating Expenses excluding Bad Debt	$2,168,050	$2,338,243	$2,588,607
Operating Income (Loss)	$165,091	$144,962	$138,045
Non-Operating Revenue	$61,540	$55,302	$58,417
Excess of Revenue over Expenses from Continuing Operations	$226,631	$200,264	$196,462

The applicant projects revenues will exceed expenses for the entire health system in each of the first three project years following completion of the proposed project.

The assumptions are reasonable, including projected utilization, costs and charges. See the Proforma Section for the proformas and assumptions. See Criterion (3) for discussion of utilization projections. Therefore, the applicant adequately demonstrates that the financial

feasibility of the proposal is based upon reasonable projections of costs and charges. Consequently, the application is conforming to this criterion.

NCDI- Holly Springs In Section VIII, page 114, the applicant states that the total capital cost of the proposed project is $2,099,869, which includes:

Construction Contract	$ 409,304
Fixed Equipment	$1,590,565
Furniture	$ 25,000
Architect & Engineering	$ 25,000
Other (Contingency)	$ 50,000
Total	$2,099,869

In Section IX, page 118, the applicant states that the total working capital required is $345,515 ($84,687 in start-up expenses + $260,828 in initial operating expenses = $345,515). In Section VIII, page 115, the applicant states that the capital costs will be funded with the accumulated reserves of Novant Health, Inc. In Attachment 20 the applicant states that the working capital costs will be funded by the reserves of Novant Health, MedQuest, Inc. and MedQuest Inc.'s line of credit with Novant Health.

Attachment 20 contains a copy of a letter dated June 9, 2010 from the Chief Financial Officer of Novant Health, Inc., which states:

> *"As the Chief Financial Officer for Novant Health, Inc., I have the authority to obligate funds from accumulated reserves of Novant Health for projects undertaken by MedQuest, Inc. and North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs ("NCDI-Holly Springs"), both affiliates of Novant Health, Inc. Novant Health, Inc. is the not-for-profit parent company of Medquest and the ultimate parent company of North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs. I am familiar with the CON application in which NCDI- Holly Springs proposes to develop a new outpatient imaging center with a fixed MRI scanner in northern Wake County.*
>
> *I can and will commit Novant's reserves to cover all of the capital costs associated with this project, including the project capital cost of $2,099,869 and start-up and initial operating expenses of $345,315."*

Attachment 20 also contains a copy of a letter dated June 9, 2010 from the Chief Accounting Officer of MedQuest, which states:

> *"This letter confirms the availability of funds for North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs ("NCDI- Holly Springs") to support the capital expenditures required for the acquisition of the fixed MRI as proposed in NCDI-Holly Spring's CON application...*

MedQuest, Inc., an affiliate of NCDI-Holly Springs, will make available all funds necessary to finance the proposed project and required working capital, as well as any unforeseen expenses related to the CON application."

Attachment 21 contains audited financial statements for Novant Health, Inc. and Affiliates for the year ended December 31, 2009. As of December 31, 2009, Novant Health, Inc. had cash and cash equivalents of $768,805,000 and total unrestricted net assets of $1,775,542,000. The applicant adequately demonstrated the availability of funds for the capital and working capital needs of the project.

The following table illustrates projected revenues, expenses and average charge per unweighted MRI procedure, as reported by the applicant in Form C and Form D. The facility does not yet exist and the applicant does not propose any service other than MRI. Therefore, the revenues and expenses in Form C (service component) are identical to those in Form B (entire facility). In Section II, page 24, the applicant states:

"NCDI- Holly Springs has not assumed any inflation in its charges during the first three years of operation following implementation. These are global charges which include both the technical component and the radiologist's professional fee. NCDI-Holly Springs will pay the radiologists, which is reflected in the expenses for the proposed project in the financial pro formas under Indirect Expenses-Professional Fees."

	Year 1- (1/1/12-12/31/12)	Year 2- (1/1/13-12/31/13)	Year 3- (1/1/14-12/31/14)
Projected # of Unweighted Procedures	3,600	4,115	4,661
Projected Average Charge (Gross Patient Revenue / Projected # of Procedures)	$2,046.18	$2,046.18	$2,046.18
Gross Patient Revenue	$7,366,232	$8,420,012	$9,537,224
Deductions from Gross Patient Revenue	$5,230,375	$5,978,610	$6,771,883
Net Patient Revenue	$2,135,856	$2,441,402	$2,765,341
Total Expenses	$1,564,969	$1,779,425	$1,875,820
Net Income	$570,887	$661,978	$889,521

As shown in the table above, the applicant projects that net revenues will exceed expenses during each of the first three operating years. The assumptions used by the applicant in preparation of the pro formas are in with the pro formas behind Section 12 of the application. However, the applicant's utilization projections are unsupported and unreliable. See Criterion (3) for discussion. Consequently, costs and revenues that are based on this projected utilization are also not reliable. Therefore, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Consequently, the application is nonconforming with this criterion.

Wake Radiology In Section VIII, page 120, the applicants state that the total capital cost of the proposed project is $1,819,102, which includes:

Construction Contract	$ 327,180
Fixed Equipment	$1,336,106
Movable Equipment	$ 37,158
Furniture	$ 3,000
Architect & Engineering	$ 33,500
Administrative & Legal	$ 41,750
Financing Costs	$ 18,500
Interest During Construction	$ 4,908
Other (freight, miscellaneous)	$ 17,000
Total	$1,819,102

In Section IX, page 118, the applicants state that there will be no startup expenses or initial operating expenses. In Section VIII, page 123, the applicants state that the capital cost will be funded with a conventional loan in the amount of $482,996 and a vendor equipment lease in the amount of $1,336,106, which total $1,819,102.

Exhibit 14 contains a copy of a letter dated June 8, 2010 from the Senior Vice President of Wells Fargo, The Private Bank, which states:

> *"We are pleased to issue this letter regarding our willingness to provide financing associated with the proposed acquisition of a fixed MRI scanner in Wake County by Wake Radiology Services, LLC, and Wake Radiology Diagnostic Imaging, Inc...Specific to this project, the Bank has examined the financial position of Wake Radiology Services, LLC and found it adequate to support the proposal. Based upon this review, the Bank is willing to provide up to $500,000 for this project, specifically to fund the leasehold improvements, contrast injector, and miscellaneous project capital costs."*

A copy of a capital lease proposal between Siemens and Wake Radiology Services, LLC dated June 4, 2010 for an Avanto RS Proven Excellence System is also contained in Exhibit 14.

Exhibit 14 also contains a copy of an asset and liability report for Wake Radiology Services as of December 31, 2009. As of December 31, 2009 Wake Radiology Services had total assets of $21,202,392.03, total liabilities of $8,175,230.00 and net assets of $13,027,163. The applicant adequately demonstrated the availability of funds for the capital and working capital needs of the project.

The following table illustrates projected revenues, expenses and average charge per unweighted MRI procedure, as reported by the applicants in Form C and Form D.

WRGO- Proposed fixed MRI service component

	Year 1- (10/1/11-9/30/12)	Year 2- (10/1/12-9/30/13)	Year 3- (10/1/13-9/30/14)
Projected # of Unweighted Procedures	3,600	4,115	4,661
Projected Average Charge (Gross Patient Revenue / Projected # of Procedures)	$1,988.71	$2,031.82	$2,070.00
Gross Patient Revenue	$7,159,352	$8,360,952	$9,648,264
Deductions from Gross Patient Revenue	$3,490,464	$4,099,147	$4,761,140
Net Patient Revenue	$3,68,888	$4,261,805	$4,887,124
Total Expenses	$2,253,997	$2,628,302	$2,884,476
Net Income	$1,414,891	$1,633,503	$2,002,648

As shown in the table above, the applicants project that net revenue for the MRI service component will exceed expenses during each of the first three operating years. The following table illustrates projected revenues and expenses for all services provided at WRGO as reported by the applicants in Form B.

WRGO- Revenue and Expenses: Entire Facility

	Project Year 1	Project Year 2	Project Year 3
Total Revenue	$6,212,418	$6,363,667	$6,463,400
Total Projected Expenses	$5,075,582	$5,295,100	$5,384,047
Net Operating Income	$1,136,837	$1,041,566	$1,079,353

As shown in the first table above, the applicants project that net revenues for the MRI service component will exceed expenses during each of the first three operating years. In addition, in the second table, the applicants project that revenues for all services provided at WRGO will exceed expenses in each of the first three operating years. The assumptions used by the applicants in preparation of the pro formas are in Section 13 of the application. However, the applicants utilization projections are unsupported and unreliable. See Criterion (3) for discussion. Consequently, costs and revenues that are based on this projected utilization are also not reliable. Therefore, the applicants did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Consequently, 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.

C – Duke Raleigh
NC- NCDI- Holly Springs
NC- Wake Radiology

Duke Raleigh Duke Raleigh adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved MRI services for the following reasons:

1) The 2010 SMFP identifies a need for one fixed MRI scanner in Wake County and the applicant proposes to acquire only one fixed MRI scanner to be located in Wake County. See Criterion (1) for additional discussion.
2) The applicant adequately demonstrates the need for a second fixed MRI scanner at Duke Raleigh Hospital. See Criterion (3) for additional discussion.

Consequently, the application is conforming to this criterion.

NCDI- Holly Springs The 2010 SMFP identifies a need for one fixed magnetic resonance imaging (MRI) scanner in Wake County and the applicant proposes to acquire only one fixed MRI scanner to be located in Wake County. See Criterion (1) for discussion. However, NCDI- Holly Springs did not adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved MRI services because the applicant did not adequately demonstrate that projected utilization was based on reasonable and supported assumptions regarding projected market share. See Criterion (3) for additional discussion. Consequently, the application is nonconforming to this criterion.

Wake Radiology The 2010 SMFP identifies a need for one fixed magnetic resonance imaging (MRI) scanner in Wake County and the applicants propose to acquire only one fixed MRI scanner to be located in Wake County. See Criterion (1) for discussion. However, Wake Radiology did not adequately demonstrate that the proposed project would not result in the unnecessary duplication of existing or approved MRI services because the applicants did not adequately demonstrate that projected utilization was based on reasonable and supported assumptions regarding projected growth between Project Years 1 and 2 and Project Years 2 and 3. See Criterion (3) for additional discussion. Consequently, 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 - All Applicants

Duke Raleigh In Section VII.1, pages 53-57, the applicant provides current and projected staffing for the existing and proposed MRI scanners. The applicant projects staffing will increase from 7.26 full-time equivalent (FTE) positions to 11.53 FTE positions at the beginning of the second year (FY2012) (.53 FTE RN positions and 3.74 FTE MR technologist positions). In Section VII.6, pages 59-61, the applicant describes its experience in the recruitment and retention of staff. In Section VII.8, page 62, the applicant identifies Josiah Carr, M.D. as the Chief of Staff/Medical director. Dr. Carr is the President of the Medical Staff and board certified in Family Medicine. The applicant also identifies Ted Kunstling, M.D. as the Chief Medical Officer for Duke Raleigh Hospital. Dr. Kunstling is board-certified in Internal Medicine and Pulmonary Disease. In Section II.8, page 24, the applicant states MRI scans are interpreted by radiologists with training and/or experience in interpreting MRI scans. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and is conforming with this criterion.

NCDI- Holly Springs In Section VII.1, pages 103-106, the applicant provides projected staffing for the proposed MRI scanner. The applicant projects a total of 5.0 FTE positions at the beginning of the second year (FY2013) (0 FTE RN positions, 5.0 FTE MR technologist positions, 1.0 clerical, 0.25 administrator, 1.0 clerical administration, .25 marketing). In Section VII.6, page 109, the applicant describes its experience in the recruitment and retention of staff. In Section II.8, page 37, the applicant identifies David Wiener, M.D. as the proposed medical director of the proposed project. Exhibit 10 contains documentation that Dr. Wiener is board-certified in radiology. Exhibit 11 contains a letter from Dr. Wiener indicating his willingness to serve as the Medical Director. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and is conforming with this criterion.

Wake Radiology In Section VII.1, pages 111-112, the applicants provide current staffing for the existing mobile MRI service and projected staffing for the proposed fixed MRI scanner. In Section VII.1, page 111, the applicants note that "*WRDI currently contracts with Alliance (the mobile MRI provider) for the MRI Technologists. Therefore, this table does not include MRI Technologists.*" The majority of the procedures are performed on a mobile MRI scanner owned by one of the applicants. The applicants did not provide the existing number of MRI technologists who support the mobile MRI scanner owned by one of the co-applicants. The applicants project a total of 4.5 FTE positions at the beginning of the second year (FY2013) 2.0 existing support and administrative positions, 2.0 FTE MRI technologist positions and 0.5 of an additional FTE support staff position. In Section VII.6, page 116, the applicants describe their experience in the recruitment and retention of staff. In Section VII.8, page 118, the applicants identify G. Glenn Coates, M.D. as the medical director of the proposed project. Dr. Coates is board-certified in radiology. The applicants demonstrate the availability of adequate health manpower and management personnel to provide the proposed services and are 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 – All Applicants

Duke Raleigh In Section II.2(a-c), page 8, the applicant describes the ancillary and support services to be provided. In Exhibit V.3, the applicant provides letters of support from referring physicians indicating their intent to refer patients to the proposed MRI scanner. The applicant adequately demonstrates that the necessary ancillary and support services will be provided and that the proposed service will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

NCDI- Holly Springs In Section II.2(a-c), page 16, the applicant describes the ancillary and support services to be provided. In Attachment 7, the applicant provides a letter from MedQuest Associates, Inc. documenting that the "*necessary ancillary and support services*

will be provided by MedQuest, as well as its parent company Novant Health, Inc." In Attachment 29, the applicant provides letters of support from referring physicians indicating their intent to refer patients to the proposed MRI scanner. The applicant adequately demonstrates that the necessary ancillary and support services will be provided and that the proposed service will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

Wake Radiology In Section II.2(a-c), pages 16-17, the applicants describe the ancillary and support services to be provided. In Exhibit 22, the applicants provide a copy of a management agreement with Wake Radiology Services, LLC to provide the ancillary and support services. In Exhibit 18, the applicants provide letters of support from referring physicians indicating their intent to refer patients to the proposed MRI scanner. The applicants adequately demonstrate that the necessary ancillary and support services will be provided and that the proposed service will be coordinated with the existing health care system. Therefore, the application is conforming with 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 – All Applicants

(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 – All Applicants

(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- Duke Raleigh
NA – NCDI- Holly Springs
NA- Wake Radiology

Duke Raleigh- To accommodate the proposed new fixed MRI scanner, the applicant proposes to construct 2,875 square feet of new space and renovate 499 square feet. See Exhibit XI.5(d) which contains a copy of the site plan. Exhibit XI.5(a) contains the architect's certified cost estimate of $2,040,000 which is consistent with the applicant's projected costs in Section VIII, page 65. In Section XI.7, page 78, the applicant states that coordinated efforts where made between the architects, engineers, and contractors to "*maintain efficient energy operations to contain the cost of utilities.*" The applicant adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. The application is conforming with 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 – Duke Raleigh
C- Wake Radiology
NA- NCDI- Holly Springs

Duke Raleigh- In Section VI.13, pages 99-100, the applicant provides the payor mix for MRI services during FY 2009 (7/1/2008 – 6/30/2009), as shown in the following table:

Duke Raleigh's Historical MRI Payor Mix

MRI Services Last Full Fiscal Year July 1, 2008 to June 30, 2009 Current Patient Days/ Procedure as Percent of Total Utilization	
Self Pay/Indigent/Charity	3.5%
Medicare/Medicare Managed Care	40.4%
Medicaid	5.8%
Commercial Insurance	47.7%
Managed Care	1.1%
Other (Specify)	1.4%
Total	**100.0%**

Note- "Other" includes out-of-state Medicaid, Tricare, and other government.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing MRI services and the application is conforming to this criterion.

Wake Radiology- In Section VI.13, page 107, the applicants provide the payor mix for the mobile MRI services provided at WRGO during FY 2009 (October 2008 – September 2009), as shown in the following table:

Wake Radiology's Historical MRI Payor Mix

MRI Services Last Full Fiscal Year October 2008 to September, 2009 Current Patient Days/ Procedure as Percent of Total Utilization	
Self Pay/Indigent/Charity	0.3%
Medicare	26.4%
Medicaid	2.7%
Managed Care/ Commercial	15.6%
Blue Cross Blue Shield	44.4%
State Employees Health Plan	10.0%
Other (Workers Comp, TriCare)	0.7%
Total	**100.0%**

The applicants demonstrate that medically underserved populations currently have adequate access to the applicants' existing mobile MRI services and 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 – Duke Raleigh
C- Wake Radiology
NA- NCDI-Holly Springs

Duke Raleigh In Section VI.10, page 49, the applicant states that *"to the best of our knowledge, no civil rights or equal access complaints have been filed by patients against Duke University Health System or any of the facilities comprising Duke University Health System in the last five years."* The application is conforming to this criterion.

Wake Radiology In Section VI.10, page105, the applicants state that *"neither WRS nor WRDI has had any civil rights complaints filed against it during 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 – All Applicants

Duke Raleigh In Section VI.2, page 44, the applicant states, *"The services of Duke Raleigh Hospital are open to all area and non-area residents for inpatient, outpatient, and other healthcare services on a walk-in, emergency, referral, or emergency basis."* In Section VI.15, pages 51-52, the applicant projects the following payor mix for the proposed MRI services in the second project year.

Duke Raleigh's Projected MRI Payor Mix

MRI Services July 1, 2011 to June 30, 2012 Projected Patient Days/ Procedure as Percent of Total Utilization	
Self Pay/Indigent/Charity	3.6%
Medicare/Medicare Managed Care	42.2%
Medicaid	8.6%
Commercial Insurance	43.1%
Managed Care	1.1%
Other (Specify)	1.4%
Total	**100.0%**

Note: "Other" includes out-of-state Medicaid, TriCare and other government.

In Section VI.15, page 52, the applicant states

"Our assumption is that the payor mix for MRI services, will change in the following ways:

- *The Medicare percentage will increase each year, with the aging of the population and the Hospital's development of services to meet their needs.*
- *The Medicaid percentage will also increase.*
- *The Managed Care percentage will go down each year as baby boomers retire and become eligible for Medicare.*
- *The commercial insurance, self-pay/indigent/charity, and other percentages will stay the same."*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services and the application is conforming to this criterion.

NCDI- Holly Springs In Section VI.2, page 91, the applicant states, *"NCDI- Holly Springs will not discriminate based on race, creed, color, sex, age, religion, national origin, mental or physical handicap, or ability to pay. NCDI- Holly Springs will be committed to providing necessary medical care to any individual regardless of that person's ability to pay."* In Section VI.15, page 102, the applicant projects the following payor mix for the proposed MRI services in the second project year.

NCDI- Holly Spring's Projected Payor Mix

MRI Services Second Full Fiscal Year 01/01/2013 – 12/31/2013 Projected Patient Days/ Procedure as Percent of Total Utilization	
Self Pay/Indigent/Charity	8.1%
Medicare/Medicare Managed Care	15.2%
Medicaid	4.8%
Commercial Insurance	6.5%
Managed Care	55.2%
Other – (Champus, Workers Compensation, Third Party Admin)	10.2%
Total	**100.0 %**

Note: *"Percentage allocation for each payor is based on historical payor mix for MedQuest sites in the region."*

In Section VI.15, page 102, the applicant states *"Percentage allocation for each payor is based on historical payor mix for MedQuest sites in the region."* The applicant does not identify the MedQuest sites in the region. However, the Agency notes that Novant Health, Inc. has an imaging facility in Cary which offers MRI services through an agreement with Kings Medical Company.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services and the application is conforming to this criterion.

Wake Radiology- In Section VI.2, the applicants state, *"WRDI will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved."* In Section VI.15, the applicants project the following payor mix for the proposed MRI services in the second project year.

Wake Radiology's Historical MRI Payor Mix

MRI Services Second Full Fiscal Year FY2013 (October 2012 to September, 2013) Current Patient Days/ Procedure as Percent of Total Utilization	
Self Pay/Indigent/Charity	0.3%
Medicare	26.4%
Medicaid	2.7%
Managed Care/ Commercial	15.6%
Blue Cross Blue Shield	44.4%
State Employees Health Plan	10.0%
Other (Workers Comp, TriCare)	0.7%
Total	**100.0%**

In Section VI.15, the applicants state "*WRDI projects the MRI payor mix for the first three project years based on the assumptions described in Section VI.14 above. In other words, WRDI projects the MRI payor mix based on the actual Garner MRI payor mix during FY2009. This table does not reflect the WRDI offer to annually provide 52 free MRI scans to Project Access patients. These "no charge" scans are reflected in the charity care section.*" The applicants demonstrate 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 – All Applicants

Duke Raleigh In Section VI.9 (a-c), pages 48-49, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.9 is reasonable and credible and supports a finding of conformity with this criterion.

NCDI- Holly Springs In Section VI.9 (a-c), pages 97-98, the applicant describes the range of means by which patients will have access to the proposed services. The information provided in Section VI.9 is reasonable and credible and supports a finding of conformity with this criterion.

Wake Radiology In Section VI.9 (a-c), page 115, the applicants describe the range of means by which patients will have access to the proposed services. The information provided in Section VI.9 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- All Applicants

Duke Raleigh- See Section V.1 (a-c), pages 39-40, for documentation that Duke Raleigh Hospital will continue to accommodate the clinical needs of area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

NCDI- Holly Springs- See Section V.1 (a-c), page 85, for documentation that NCDI- Holly Springs will accommodate the clinical needs of area health professional training programs. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

Wake Radiology- See Section V.1 (a-c), page 102, for documentation that the applicants will continue to accommodate the clinical needs of area health professional training programs. 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.

C – Duke Raleigh
NC – NCDI- Holly Springs
NC – Wake Radiology

Duke Raleigh- The applicant adequately demonstrated that the proposal would have a positive impact on the cost effectiveness, quality, and access to the proposed services for the following reasons: 1) the applicant adequately demonstrates the proposal is cost-effective [See Criteria (1), (3) and (5) for additional discussion]; 2) the applicant demonstrates it will provide adequate access to the proposed services [See Criterion (13) for additional discussion]; and 3) the applicant adequately demonstrates it has and will continue to provide quality MRI services [See Criteria (7), (8), and (20) for additional discussion]. Therefore, the application is conforming to this criterion.

NCDI- Holly Springs- The applicant did not adequately demonstrate that the proposal is cost effective because the applicants projected utilization is not based on reasonable and supported assumptions. Therefore, the applicant's costs and revenue are unreliable and the applicant did not adequately demonstrate the proposal would maximize healthcare value.

See Criteria (1), (3) and (5) for additional discussion. Therefore the application is nonconforming to this criterion.

Wake Radiology- The applicants did not adequately demonstrate that the proposal is cost effective because the applicants projected utilization is not based on reasonable and supported assumptions. Therefore, the applicants' costs and revenue are unreliable and the applicants did not adequately demonstrate the proposal would maximize healthcare value. See Criteria (1), (3) and (5) 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- Duke Raleigh
NA – NCDI- Holly Springs
NA- Wake Radiology

Duke Raleigh- Duke Raleigh Hospital is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred, 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 with 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.

C – Duke Raleigh
NC- NCDI-Holly Springs
NC- Wake Radiology

Duke Raleigh The proposal is conforming to all Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

NCDI- Holly Springs The proposal is not conforming to all Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

Wake Radiology The proposal is not conforming to all Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700. The specific criteria are discussed below.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care Facility/Medical Equipment application form.

-C- **All Applicants** used the Acute Care Facility/Medical Equipment application form.

(b) Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant and the person billing the patients for the MRI service shall be named as co-applicants in the application form.

-C- **Duke Raleigh-** In Section II.8, page 13, the applicant, Duke Raleigh, states that it is both the applicant and the entity billing patients for MRI services.

-C- **NCDI-Holly Springs-** In Section II.8, page 23, the applicant, NCDI-Holly Springs, states that it is both the applicant and the entity billing patients for MRI services.

-C- **Wake Radiology-** In Section II.8, page 29, the applicants state that one of the applicants, WRDI, will be the entity billing patients for MRI services.

(c) An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:

(1) documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI scanners, will be available and staffed for use at least 66 hours per week;

-C- **Duke Raleigh-** In Section II.4, pages 8-9, the applicant states that the proposed fixed MRI scanner will be staffed and operated a total of 70 hours each week (8am-10pm on weekdays).

-C- **NCDI-Holly Springs-** In Section II.8, page 23, the applicant states "*NCDI-Holly Springs will ensure that the proposed MRI scanner will be available and staffed at least 66 hours per week. The proposed unit will operate Monday through Friday 8:00am to 8:00pm and Saturday from 8:00am to 4:00pm for a total of 68 hours per week.*"

-C- **Wake Radiology-** In Section II.8, page 30, the applicant states "*The proposed MRI scanner will be staffed from 7:00 am to 7:00 pm Monday through Friday and Saturday 8:00am to 2:00pm (66 hours) each week.*"

(2) documentation that the proposed mobile MRI scanner will be available and staffed for use at least 40 hours per week;

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(3) documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be available and staffed for use at least 40 hours per week;

-NA- **None of the applicants** propose to acquire either a fixed extremity or a dedicated breast MRI scanner.

(4) the average charge to the patient, regardless of who bills the patient, for each of the 20 most frequent MRI procedures to be performed for each of the first three years of operation after completion of the project and a description of items included in the charge; if the professional fee is included in the charge, provide the dollar amount for the professional fee;

-C- **Duke Raleigh-** In Section II.8, page 13, and Exhibit II.8A, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during the first three years of operation. The applicant states that the charges do not include the professional fees, which are billed separately.

-C- **NCDI-Holly Springs-** In Section II.8, pages 24-25, the applicant provides the projected charges for the 20 MRI procedures to be performed most frequently during the first three years of operation. The applicant states that "*these are global charges which include both the technical component and the radiologist's professional fee.*" The applicant provides the dollar amount of the professional fee in Section II.8, page 25.

-C- **Wake Radiology-** In Section II.8, pages 30-31, the applicants provide the projected charges for the 20 MRI procedures to be performed most frequently during the first three years of operation. On page 31, the applicants provide both the projected global charge and the dollar amount of the professional fee.

(5) if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of the service contract fee billed by the applicant to the contracting party for each of the first three years of operation;

-NA- **None of the applicants** propose to provide the MRI services pursuant to a service agreement.

(6) letters from physicians indicating their intent to refer patients to the proposed magnetic resonance imaging scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals;

-C- **Duke Raleigh-** Exhibit V.3 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals for MRI studies.

-C- **NCDI- Holly Springs-** Attachment 29 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner and their estimate of the number of patients proposed to be referred per year, which is based on the physicians' historical number of referrals for MRI studies.

-C- **Wake Radiology-** Exhibit 18 contains letters from physicians indicating their intent to refer patients to the proposed fixed MRI scanner and their estimate of the number of patients proposed to be referred per year, the physicians' historical number of referrals for MRI studies.

(7) for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, the number of fixed MRI scanners operated or to be operated at each location;

-C- **Duke Raleigh Hospital-** In Section II.8, page 14, the applicant states that the only location in the MRI service area (Wake County) at which Duke University Health System or a related entity will provide MRI services utilizing a fixed MRI scanner is on the campus of Duke Raleigh Hospital. Duke University Health System currently has one fixed MRI scanner located on the Duke Raleigh Hospital campus. The proposed MRI scanner would also be located on the Duke Raleigh Hospital campus.

-C- **NCDI- Holly Springs-** In Section II.8, page 26, the applicant states that NCDI- Holly Springs, MedQuest, and Novant do not currently operate any fixed MRI scanners in the MRI service area (Wake County). NCDI- Holly Springs proposes to operate one fixed MRI scanner at 190 Rosewood Centre Drive in Holly Springs.

-C- **Wake Radiology-** In Section II.8, page 32, WRDI (a co-applicant) states that it currently operates two (2) fixed MRI scanners at Raleigh MRI located on Merton Drive in Raleigh. The proposed fixed MRI would be operated at the WRGO facility in Garner. Both locations are in Wake County. In addition, the applicants state *"For information purposes, the applicants provide MRI services at the Wake Radiology-Cary office via a fixed MRI scanner owned by Alliance. The applicants do not have any ownership interest in this fixed MRI scanner, thus it is not subject to this rule. This was confirmed via telephone call with CON Project Analyst Mike McKillip on June 10, 2010."*

(8) for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of unweighted MRI procedures to be

performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;

-C- **Duke Raleigh Hospital-** In Section IV.1, page 35 and Exhibit IV.1, the applicant provides projections of the number of unweighted MRI procedures for each of the four types of MRI procedures to be performed on the existing fixed MRI scanner and on the proposed fixed MRI scanner for the first three years following completion of the project. See Criterion (3) for discussion of reasonableness of projections.

-C- **NCDI- Holly Springs-** In Section II.8, page 26, the applicant provides projections of the number of unweighted MRI procedures for each of the two types of MRI procedures to be performed on the proposed fixed MRI scanner for the first three years following completion of the project. The applicant does not propose to perform MRI procedures on inpatients. See Criterion (3) for discussion of reasonableness of projections.

-C- **Wake Radiology-** In Section II.8, pages 32-33, the applicants provide projections of the number of unweighted MRI procedures for each of the two types of MRI procedures to be performed on the proposed fixed MRI scanner for the first three years following completion of the project. The applicant does not propose to perform MRI procedures on inpatients. See Criterion (3) for discussion of reasonableness of projections.

(9) for each location in the MRI service area at which the applicant or a related entity will provide services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;

-C- **Duke Raleigh Hospital-** In Section IV.1, page 35 and Exhibit IV.1, the applicant provides projections of the number of weighted MRI procedures for each of the four types of MRI procedures to be performed on the existing fixed MRI scanner and on the proposed fixed MRI scanner for the first three years following completion of the project. See Criterion (3) for discussion of reasonableness of projections.

-C- **NCDI- Holly Springs-** In Section II.8, page 27, the applicant provides projections of the number of weighted MRI procedures for each of the two types of MRI procedures to be performed on the proposed fixed MRI scanner for the first three years following completion of the project. The applicant does not propose to perform MRI procedures on inpatients. See Criterion (3) for discussion of reasonableness of projections.

-C- **Wake Radiology-** In Section II.8, pages 34-35, the applicants provide projections of the number of unweighted MRI procedures for each of the two types of MRI procedures to be performed on the proposed fixed MRI scanner for the first three years following completion of the project. The applicants do not propose to perform MRI procedures on inpatients. See Criterion (3) for discussion of reasonableness of projections.

(10) a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures to be performed at each location, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus outpatient procedures;

-C- **Duke Raleigh Hospital-** The applicant's methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures and inpatient versus outpatient procedures, are described in Section II.8, page 15, Section III.1, pages 27-29, and Exhibit IV.1. See Criterion (3) for discussion of reasonableness of projections.

-C- **NCDI- Holly Springs-** The applicant's methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures, are described in Section II.8, page 27, and Section III.1, pages 40-71. The applicant does not propose to provide MRI procedures to inpatients or use sedation. See Criterion (3) for discussion of reasonableness of projections.

-C- **Wake Radiology-** The applicants' methodology and assumptions used to project the number of unweighted MRI procedures, including the number of contrast versus non-contrast procedures, are described in Section II.8, pages 35-37, Section III.1, pages 59-86, and Section IV.1, pages 99-100. The applicants do not propose to provide MRI procedures to inpatients or use sedation. See Criterion (3) for discussion of reasonableness of projections.

(11) a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;

-C- **Duke Raleigh Hospital-** The applicant's methodology and assumptions used to project the number of weighted MRI procedures are described in Section II.8, page 16, Section III.1, pages 27-29, and Exhibit IV.1. See Criterion (3) for discussion of reasonableness of projections.

-C- **NCDI- Holly Springs-** The applicant's methodology and assumptions used to project the number of weighted MRI procedures are described in Section II.8, page 27, Section III.1, pages 40-71. The applicant does not propose to provide MRI procedures to inpatients or use sedation. See Criterion (3) for discussion of reasonableness of projections.

-C- **Wake Radiology-** The applicants' methodology and assumptions used to project the number of weighted MRI procedures are described in Section II.8, page 38, Section III.1, pages 59-86, and Section IV.1, pages 99-100. The applicants do not propose to provide MRI procedures to inpatients or use sedation. See Criterion (3) for discussion of reasonableness of projections.

(12) for each existing, approved or proposed mobile MRI scanner owned by the applicant or a related entity and operated in North Carolina in the month the application is submitted, the vendor, tesla strength, serial number or vehicle identification number, CON project identification number, and host sites;

-CA- **Duke Raleigh-** In Section II.8, pages 16-17, the applicant states *"The only mobile scanner owned by DUHS or a related entity is sited at Lenox Baker at Duke Hospital. Pursuant to an agreement with the Certificate of Need Section, it is moved only one week per year, and the procedures it provides are reported with those of the other clinical scanners operated by the Department of Radiology at Duke Hospital."* However, the applicant does not provide the tesla strength, serial number or VIN, and host sites. The tesla strength and serial number are available in publicly available files in the Division of Health Service Regulation. However, those files do not show the host sites at the time the application was submitted. Therefore, the application is conforming to this rule subject to the following condition:

> **Prior to issuance of the Certificate of Need, Duke University Health System d/b/a Duke Raleigh Hospital shall provide the Certificate of Need Section with the host sites for the mobile scanner owned by Duke University Health System.**

-C- **NCDI- Holly Springs-** In Section II.8, page 28, the applicant provides a list of the existing, and approved mobile MRI scanners owned by the applicant or a related entity and operated in North Carolina which list includes the vendor, tesla strength, serial number, CON project identification number and host sites.

-NC- **Wake Radiology-** In Section II.8, page 39, the applicant states that WRS owns a mobile MRI which is operated by WRDI. The vendor is Siemens; Tesla- 1.5T; Serial Number 25432; and CON Project ID# J-7012-04. However, the applicants did not provide the host sites at the time the application was submitted and this information is not available in publicly available files in the Division of Health Service Regulation. Therefore, the application is nonconforming to this rule.

(13) for each host site in the mobile MRI region in which the applicant or a related entity will provide the proposed mobile MRI services, utilizing existing, approved, or proposed mobile MRI scanners, projections of the annual number of unweighted and weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(14) if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI scanner; and

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(15) identity of the accreditation authority the applicant proposes to use.

-C- **Duke Raleigh-** In Section II.8, page 17, the applicant states "*Duke Raleigh Hospital is accredited by the Joint Commission.*"

-C- **NCDI- Holly Springs-** In Section II.8, page 29, the applicant states "*NCDI- Holly Springs will seek American College of Radiology (ACR) accreditation for the proposed MRI scanner.*"

-C- **Wake Radiology-** In Section II.8, page 42, the applicants state "*Relevant to the proposed fixed MRI scanner, Wake Radiology will seek MRI accreditation from the American College of Radiology during the first year of the proposed project.*"

(d) An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and proposed contracts with, all of the proposed host facilities of the new MRI scanner.

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(e) An applicant proposing to acquire a dedicated fixed breast MRI scanner shall demonstrate that:

(1) it has an existing and ongoing working relationship with a breast-imaging radiologist or radiology practice group that has experience interpreting breast images provided by mammography, ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI scanner configured exclusively for mammographic studies;

(2) for the last 12 months it has performed the following services, without interruption in the provision of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms, breast ultrasound procedures, breast needle core biopsies, breast cyst aspirations, and pre-surgical breast needle localizations;

(3) its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI scanner is in compliance with the federal Mammography Quality Standards Act;

(4) it is part of an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the geographic area proposed to be served by the applicant; and,

(5) it has an existing relationship with an established collaborative team for the treatment of breast cancer that includes, radiologists, pathologists, radiation oncologists, hematologists/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.

-NA- **None of the applicants** propose to acquire a dedicated fixed breast MRI scanner.

(f) An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:

(1) *provide a detailed description of the scope of the research studies that will be conducted to demonstrate the convenience, cost effectiveness and improved access resulting from utilization of extremity MRI scanning;*

(2) *provide projections of estimated cost savings from utilization of an extremity MRI scanner based on comparison of "total dollars received per procedure" performed on the proposed scanner in comparison to "total dollars received per procedure" performed on whole body scanners;*

(3) *provide projections of estimated cost savings to the patient from utilization of an extremity MRI scanner;*

(4) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*

(A) a detailed description of the research studies completed;

(B) a description of the results of the studies;

(C) the cost per procedure to the patient and billing entity;

(D) the cost savings to the patient attributed to utilization of an extremity MRI scanner;

(E) an analysis of "total dollars received per procedure" performed on the extremity MRI scanner in comparison to "total dollars received per procedure" performed on whole body scanners; and

(F) the annual volume of unweighted and weighted MRI procedures performed, by CPT code;

(5) *identify the operating hours of the proposed scanner;*

(6) *provide a description of the capabilities of the proposed scanner;*

(7) *provide documentation of the capacity of the proposed scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour;*

(8) *identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;*

(9) *provide copies of the operational and safety requirements set by the manufacturer; and*

(10) *describe the criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.*

-NA- **None of the applicants** propose to acquire an extremity MRI scanner.

(g) *An applicant proposing to acquire a multi-position MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:*

(1) *commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that will include:*

(A) the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;

(B) the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;

(C) *the number of doctors by specialty that referred patients for an MRI scan in an upright or nonstandard position;*

(D) *documentation to demonstrate compliance with the Basic Principles policy included in the State Medical Facilities Plan;*

(E) *a detailed description of the unique information that was acquired only by use of the multi-position capability of the multi-position MRI scanner; and*

(F) *the number of insured, underinsured, and uninsured patients served by type of payment category;*

(2) *provide the specific criteria that will be used to determine which patients will be examined in other than routine supine or prone imaging positions;*

(3) *project the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;*

(4) *project the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;*

(5) *demonstrate that access to the multi-position MRI scanner will be made available to all spine surgeons in the proposed service area, regardless of ownership in the applicant's facility;*

(6) *demonstrate that at least 50 percent of the patients to be served on the multi-position MRI scanner will be spine patients who are examined in an upright or nonstandard position; and*

(7) *provide documentation of the capacity of the proposed fixed multi-position MRI scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour.*

-NA- **None of the applicants** propose to acquire a multi-position MRI scanner.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:

(1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*

(2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located*

[Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and

(3) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

-C- **Duke Raleigh**- In Section II.8, page 20, the applicant states that the one existing fixed MRI scanner at Duke Raleigh performed 6,893 weighted procedures for the 12 months ending May 31, 2010.

-NA- **NCDI- Holly Springs**- In Section II.8, pages 33-34, the applicant states neither NCDI-Holly Springs nor a related entity own an existing fixed MRI scanner in Wake County.

-C- **Wake Radiology**- In Section II.8, pages 46-47, the applicant states that Raleigh MRI, a related entity, operated two (2) fixed MRI scanners in the MRI service area (Wake County) which performed a total of 10,079 weighted MRI procedures during the 12 months ending September 30, 2009, which is an average of 5,039 weighted MRI procedures per scanner.

(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

-NA- **Duke Raleigh**- In Section II.8, page 21, the applicant states that neither Duke University Health System nor a related entity owns a controlling interest in a mobile MRI scanner that operates in the MRI service area (Wake County).

-NA- **NCDI- Holly Springs**- In Section II.8, pages 33-34, the applicants states *"Novant Health, Inc. owns North Carolina Diagnostic Imaging-Cary, which is currently receiving mobile MRI services from Kings Medical Company, an independent third party provider. Neither Novant Health, Inc., nor any of its related entities including MedQuest and NCDI-Holly Springs, has any ownership interest in Kings Medical Company or its MRI scanners. There are no Novant-owned mobile MRI scanners operating in Wake County at this time of this filing."*

-C- **Wake Radiology-** In Section II.8, page 47, the applicant's state that WRS owns and WRDI operates one mobile MRI scanner in the MRI service area which performed 3,560 weighted MRI procedures during the 12 months ending September 30, 2009.

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

The 2010 SMFP shows more than four (4) fixed MRI scanners located in the MRI service area, which consists of Wake County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed MRI scanners which the applicant or a related entity owns and locates in Wake County is reasonably expected to perform 4,805 weighted MRI procedures per scanner in the third operating year.

-C- **Duke Raleigh-** The applicant will have a total of two existing, approved and proposed fixed MRI scanners located in Wake County by the third operating year of this project. In Section II.8, page 21, and Table IV, page 35, the applicant projects to perform 8,034 unweighted MRI procedures in the third operating year, which the applicant states equals 10,538 weighted procedures. This results in an average annual utilization of 5,269 weighted procedures per MRI scanner in the third year. The applicant adequately demonstrates that its projections are based on reasonable and supported assumptions. See Criterion (3) for discussion.

-NC- **NCDI- Holly Springs-** The applicant will have a total of one existing, approved and proposed fixed MRI scanner by the third operating year of this project. In Section II.8, page 34, the applicant projects to perform 5,025 weighted procedures in the third operating year. However, the applicant did not adequately demonstrate that its projections are based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming to this rule.

-NC- **Wake Radiology-** The applicants will have a total of three existing and proposed fixed MRI scanners by the third operating year of this project (Wake Radiology does not have any approved fixed MRI scanners). In Section II.8, page 34, the applicants project the average annual utilization of the existing and proposed fixed MRI scanners (2 existing at Raleigh

MRI and 1 proposed at WRGO) will be 4,896 weighted MRI procedures (4,945 on proposed fixed MRI scanner at WRGO + 9,744 on the two existing MRI scanners at Raleigh MRI = 14,689/3 MRI scanners = 4,896) in the third operating year.

However, the applicants did not adequately demonstrate that the existing and proposed fixed MRI scanners would reasonably perform an average of at least 4,805 weighted MRI procedures in the third operating year.

The applicants used the following assumptions and methodology to project utilization of the two existing fixed MRI scanners at Raleigh MRI.

First, the applicants started with the actual number of MRI procedures performed in FY2009 on the two fixed MRI scanners located at Raleigh MRI and projected a 2.2% increase in unweighted MRI procedures for each year from FY2010 through FY2014. (See Section II.8, pages 35-36). The table below illustrates the historical and projected unweighted and weighted MRI procedures for the two fixed MRI scanners at Raleigh MRI.

Raleigh MRI Projected Utilization

	FY2009	FY 2010 Projected-Interim	FY 2011 Projected-Interim	PY1 FY 2012	PY2 FY 2013	PY3 FY 2014
Unweighted MRI Procedures	8,546	8,731	8,919	9,112	9,309	9,511
Weighted MRI Procedures	10,078	10,297	10,519	10,747	10,979	11,216
% change in weighted	<11.85%>.	2.2%	2.2%	2.2%	2.2%	2.2%

Second, the applicants then stated that WRDI would locate its mobile MRI scanner at Raleigh MRI for three days per week and assume 1,248 of those unweighted MRI procedures would be performed on the mobile MRI scanner, as illustrated in the table below. (See Section II.8, pages 36-37.)

Raleigh MRI Projected Utilization

	FY2012	FY2013	FY2014
Fixed MRI procedures	7,864	8,061	8,263
Mobile MRI procedures	1,248	1,248	1,248
Total unweighted MRI procedures	9,112	9,309	9,511

Third, the applicants then converted the unweighted fixed MRI procedures not allocated to the mobile MRI scanner to weighted MRI procedures as shown in the table below.

	FY2012	FY2013	FY2014
Unweighted MRI procedures	7,864	8,061	8,263
Weighted MRI procedures	9,275	9,507	9,744

The applicants assume the two existing fixed MRI scanners at Raleigh MRI will perform 9,744 weighted MRI procedures in Year 3, which is an average of 4,872 weighted MRI

procedures per scanner [9,744/ 2 = 4,872 weighted MRI procedures per MRI scanner]. As noted above, the proposed fixed MRI scanner at WRGO is projected to perform 4,945 weighted MRI procedures in year 3. Thus, the three fixed MRI scanners (2 at Raleigh MRI and one proposed at WRGO) are projected to average 4,896 weighted MRI procedures.

However, Wake Radiology did not adequately demonstrate that projected utilization of the proposed fixed MRI scanner at WRGO is based on reasonable and supported assumptions. See discussion in Criterion (3).

Furthermore, the applicants did not adequately demonstrate that it is reasonable to assume volume at Raleigh MRI would increase 2.2% per year from FY 2010 to FY2014. The table below illustrates historical and projected utilization of the two fixed MRI scanners at Raleigh MRI.

Raleigh Fixed MRI Utilization (Historical and Projected)

	FY2005	FY2006	FY2007	FY2008	FY2009	FY 2010 Projected-Interim	FY 2011 Projected-Interim	PY1 FY 2012	PY2 FY 2013	PY3 FY 2014
Unweighted	11,852	10,576	10,009	9,842	8,546	8,731	8,919	9,112	9,309	9,511
Weighted	13,204	11,837	11,308	11,272	10,078	10,297	10,519	10,747	10,979	11,216
% change in weighted	-na-	<11.55%>	<4.7%>	<0.32%>	<11.85%>.	2.2%	2.2%	2.2%	2.2%	2.2%

As shown above, for each year from FY2005 to FY2009, the number of MRI procedures performed on the two fixed MRI scanners at Raleigh MRI has decreased. The applicants do not provide an explanation for this other than to state that the economy was difficult in FY2008. Furthermore, the applicants do not adequately document that it is reasonable to assume volume at Raleigh MRI will increase except to state in Section II.8, page 35, "*During FY2009, WRDI performed 8,546 unweighted MRI scans on the two fixed MRI scanners located at Raleigh MRI. To project MRI utilization at Raleigh MRI through FY2014, WRDI conservatively applied three-fourths of the projected population growth rate for Wake County (2.9% x .75 = 2.2%) to its most recent historical MRI utilization.*" The applicants tied MRI growth at Raleigh MRI to population growth. However, as shown in Section III.1, page 64, the population of Wake County increased at a compound annual growth rate ("CAGR") of 4.2% from FY2004 to FY2009, the same years during which utilization of the two fixed MRI scanners at Raleigh MRI declined every year.

In addition, as shown in Section III.1, page 65, the overall number of weighted MRI procedures performed in Wake County (on both fixed and mobile MRI scanners) increased by 9.3% between FY2008 and FY2009 while the number of weighted MRI procedures performed on the two fixed MRI scanners at Raleigh MRI decreased by 11.85% from FY2008 to FY2009.

In summary, Wake Radiology did not adequately demonstrate that its existing and proposed fixed MRI scanners are reasonably expected to perform an average of at least 4,805 weighted MRI procedures per scanner in the third operating year.

Therefore, the application is nonconforming to this rule.

(4) *if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

- *(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*
- *(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*
- *(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*
- *(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*
- *(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

-NA- **Duke Raleigh-** In Section II.8, page 22, the applicant states that the proposed MRI scanner will not be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity which are located in the MRI service area (Wake County).

-NA- **NCDI- Holly Springs-** In Section II.8, page 35, the applicant states that the proposed MRI scanner would be the only MRI scanner owned by the applicant or a related entity in the MRI service area (Wake County).

-NC- **Wake Radiology-** In Section II.8, page 34, the applicants state they will have a total of three existing, approved and proposed fixed MRI scanners by the third operating year of this project, which are located in the MRI service area (Wake County) (2 existing fixed MRI scanners at Raleigh MRI and proposed fixed MRI scanner at WRGO). In Section II.8, page 34, the applicants project the annual utilization of the proposed fixed MRI scanner at WRGO would be 4,945 weighted procedures in the third project year. However, the applicants did not adequately demonstrate that projected utilization of the proposed fixed MRI scanner at WRGO is based on reasonable and supported assumptions. See Criterion (3) for discussion. Therefore, the application is nonconforming to this rule.

(5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*

-NA- **Duke Raleigh-** In Section II.8, page 22, the applicant states that *"neither Duke University Health System nor a related entity owns a controlling interest in a mobile MRI scanner operated in the service area."*

-NA- **NCDI- Holly Springs-** In Section II.8, pages 33-34, the applicant states *"Novant Health, Inc. owns North Carolina Diagnostic Imaging-Cary, which is currently receiving mobile MRI services from Kings Medical Company, an independent third party provider. Neither Novant Health, Inc., nor any of its related entities including MedQuest and NCDI-Holly Springs, has any ownership interest in Kings Medical Company or its MRI scanners. There are no Novant-owned mobile MRI scanners operating in Wake County at this time of this filing."*

-NC- **Wake Radiology-** In Section II.8, page 47, the applicants state that WRS owns and WRDI operates one mobile MRI scanner in the MRI service area (Wake County). In Section II.8, pages 39-41, the applicants project the mobile MRI scanner will perform 3,484 weighted procedures in Year 3. In Section II.8, pages 39-41, the applicants provide *"projected unweighted and weighted MRI utilization by site for WRDI's existing mobile MRI scanner. For information purposes, mobile MRI services are currently offered at each of the sites identified in the following tables."* See the following tables.

Raleigh MRI- Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2007	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures	350	432	19	-na-	-na-	1,248	1,248	1,248
Weighted MRI Procedures						1,406	1,406	1,406

Wake Radiology Northwest Raleigh Office
Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures	-na-	20*	—	—	728	832	936
Weighted MRI Procedures	-na-				815	932	1,048

*9/1/09 – 9/30/09 only. Total of 36 hours.

Wake Radiology Wake Forest Office
Historical and Projected Mobile MRI Procedures FY2012-FY2014

	2008	2009	2010	2011	2012	2013	2014
Unweighted MRI Procedures					728	832	936
Weighted MRI Procedures					801	915	1,030

No Data for 2008-2011.

The table below illustrates the total projected unweighted and weighted MRI procedures for FY2012-FY2014 for all three of the listed host sites.

Total- All Three Projected Host Sites
Projected Mobile MRI Procedures FY2012-FY2014

	2012	2013	2014
Total Unweighted MRI Procedures	2,704	2,912	3,120
Total Weighted MRI Procedures	3,022	3,253	3,484

However, projected utilization of the mobile MRI scanner at Raleigh MRI is based on projected utilization of the fixed MRI scanners at Raleigh MRI. Projected utilization of the fixed MRI scanners at Raleigh MRI is not based on reasonable and supported assumptions. See discussion in 10A NCAC 14C .2703(b)(3). Therefore, projected utilization of the mobile MRI scanner at Raleigh MRI is also questionable.

Furthermore, Wake Radiology did not provide the methodology and assumptions used to project utilization of the mobile MRI scanner at the two other host sites: Northwest Raleigh Office and Wake Forest Office other than to state "*For information purposes, mobile MRI services are currently offered at each of the sites identified in the following tables.*" [See Section II.8, pages 39-41.] In Section II.8, page 47, the applicants did state that for the 12-month period ending September 30, 2009, 20 unweighted/ 22 weighted MRI procedures were performed at the Northwest Raleigh Office. Wake Radiology did not supply any year-to-date information as to the number of MRI procedures (either unweighted or weighted) performed at either the Northwest Raleigh Office or the Wake Forest Office after September 30, 2009. This application was submitted on June 15, 2010, almost nine months later.

The applicants do not adequately demonstrate projected utilization of the existing mobile MRI scanner is based on reasonable and supported assumptions. Consequently, the applicants did not adequately demonstrate that the mobile MRI scanner is reasonably expected to perform 3,328 weighted MRI procedures in Year 3. Therefore, the application is nonconforming with this rule.

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-C- **Duke Raleigh-** The applicant adequately documented the assumptions and provided data supporting the methodology used for each projection required in this rule. See Criterion (3) for discussion.

-NC- **NCDI- Holly Springs-** The applicant did not adequately document the assumptions and provide data supporting the methodology used for each projection required by this rule. See Criterion (3) for discussion. Therefore, the application is nonconforming with this rule.

-NC- **Wake Radiology-** The applicants did not adequately document the assumptions and provide data supporting the methodology used for each projection required by this rule. See Criterion (3) for discussion. See also discussion in 10A NCAC 14C .2703 (b)(3)) and 10A NCAC 14C .2703 (b)(5). Therefore, the application is nonconforming with this rule.

(c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-NA- **None of the applicants** propose to acquire a fixed dedicated breast MRI scanner.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

(1) demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-NA- **None of the applicants** propose to acquire a fixed extremity MRI scanner.

(e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*

(1) demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and

(2) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

-NA- **None of the applicants** propose to acquire a fixed multi-position MRI scanner.

10A NCAC 14C .2704 SUPPORT SERVICES

(a) *An applicant proposing to acquire a mobile MRI scanner shall provide referral agreements between each host site and at least one other provider of MRI services in the geographic area to be served by the host site, to document the availability of MRI services if patients require them when the mobile unit is not in service at that host site.*

NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(b) *An applicant proposing to acquire a fixed or mobile MRI scanner shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the American College of Radiology or a comparable accreditation authority, as determined by the*

Certificate of Need Section, for magnetic resonance imaging within two years following operation of the proposed MRI scanner.

-C- **Duke Raleigh**- The hospital is currently accredited by the Joint Commission. See Section II.8, page 23.

-C- **NCDI- Holly Springs**- In Section II.8, page 37, the applicant states NCDI-Holly Springs will obtain accreditation from the American College of Radiology for the proposed MRI services.

-C- **Wake Radiology**- In Section II.8, page 56, the applicants state that they will seek MRI accreditation from the American College of Radiology during the first year of the proposed project.

10A NCAC 14C .2705 STAFFING AND STAFF TRAINING

(a) An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that one diagnostic radiologist certified by the American Board of Radiologists shall be available to interpret the images who has had:

(1) training in magnetic resonance imaging as an integral part of his or her residency training program; or

(2) six months of supervised MRI experience under the direction of a certified diagnostic radiologist; or

(3) at least six months of fellowship training, or its equivalent, in MRI; or

(4) a combination of MRI experience and fellowship training equivalent to Subparagraph (a)(1), (2) or (3) of this Rule.

-C- **Duke Raleigh**- In Section II.8, page 24, the applicant states "*The radiologists interpreting MRI scans at Duke Raleigh Hospital all meet the listed requirements. The radiologists include both members of Duke Radiology of Raleigh, who hold consulting appointments on the faculty of the Department of Radiology of the Duke University School of Medicine, and regular rank faculty members.*" Exhibit II.8 B contains copies of the curriculum vitae of a member of Duke Radiology of Raleigh and a faculty member which document that both physicians are board-certified radiologists with the training and experience required by this Rule.

-C- **NCDI- Holly Springs**- In Section II.8, page 37, the applicant states "*Radiology coverage for NCDI-Holly Springs will be provided by Durham Radiology. Durham Radiology currently has an established working relationship with Novant/MedQuest and provides profession* [sic] *coverage at other existing MedQuest Imaging Centers, including NCDI-Cary. Dr. David Wiener, who is a board-certified radiologist with specialty training in MRI, will serve as Medical Director.*" Attachment 10 contains a copy of the curriculum vitae of Dr. Wiener which documents that he is a board-certified radiologist with the training and experience required by this Rule.

-C- **Wake Radiology**- In Section II.8, page 56, the applicants state "*Please refer to Exhibit 3 for a letter from Dr. Coates documenting compliance with the above criterion, and indicating his intention to serve as the MRI Medical Director.*" Exhibit 3 contains a copy of the curriculum

vitae of Dr. Coates which documents that he is a board-certified radiologist with the training and experience required by this Rule.

(b) An applicant proposing to acquire a dedicated breast MRI scanner shall provide documentation that:

(1) the radiologist. is trained and has expertise in breast imaging, including mammography, breast ultrasound and breast MRI procedures; and

(2) two full time MRI technologists or two mammography technologists are available with training in breast MRI imaging and that one of these technologists shall be present during the hours operation of the dedicated breast MRI scanner.

-NA- **None of the applicants** propose to acquire a dedicated breast MRI scanner.

(c) An applicant proposing to acquire a MRI scanner, including extremity but excluding dedicated breast MRI scanners, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.

-C- **Duke Raleigh-** In Section II.8, page 24, the applicant proposes a total of 9.47 FTE MRI technologist positions. The applicant states that at least one of the technologists will be present during all the hours of operation of the MRI scanner.

-C- **NCDI- Holly Springs-** In Section II.8, page 38, the applicant proposes 2.5 FTE MRI technologist positions. The applicants state that at least one technologist will be present during all hours of operation of the MRI scanner.

-C- **Wake Radiology-** In Section II.8, page 57, the applicants propose 2.0 FTE MRI technologist positions. The applicants state that at least one MRI technologist will be present during all hours of operation.

(d) An applicant proposing to acquire an MRI scanner, including extremity and breast MRI scanners, shall demonstrate that the following staff training is provided:

(1) American Red Cross or American Heart Association certification in cardiopulmonary resuscitation (CPR) and basic cardiac life support; and

-C- **Duke Raleigh-** In Section II.8, page 25, the applicant states "*All Duke Raleigh Hospital's technologists are required by the Hospital and the Joint Commission to receive American Heart Association certification in Cardiopulmonary Resuscitation (CPR) training and basic cardiac life support... Nursing personnel have completed an AMA nurse training program and have taken and passed the respective boards.*"

-C- **NCDI- Holly Springs-** In Section II. 8, pages 38-39, the applicant states "*NCDI-Holly Springs will require that its entire clinical staff have and maintain current certification in cardiopulmonary resuscitation and basic cardiac life support and will ensure that appropriate opportunities to obtain such training are available to all staff. All staff education and training will be provided by MedQuest Associates, Inc. MedQuest Associates*

Inc. has an established training program that is implemented in each of its managed facilities which includes all of the above training." Attachment 12 includes documentation regarding the availability of staff education and training programs.

-C- **Wake Radiology-** In Section II.8, page 57, that applicants state that they will "*continue to provide continuing education programs for Garner staff including CPR and BCLS training for appropriate clinical staff.*" Exhibit 6 contains copies of the applicants Orientation, Continuing Education Policy and CPR certification.

(2) the availability of an organized program of staff education and training which is integral to the services program and ensures improvement in technique and the proper training of new personnel.

-C- **Duke Raleigh-** In Section II.8, page 25, the applicant states "*All Duke Raleigh Hospital MRI technologists have completed the AMA radiologists training program and have taken and passed the American Registry of Technologists (AART) national boards. In addition, the technologists are required to take and pass the Advanced Level Certification (ALC) in Magnetic Resonance Imaging by the AART. Nursing personnel have completed an AMA nurse training program and have taken and passed the respective boards. A minimum of one year's experience in a clinical care unit is also required.*" Exhibit II.7 contains a copy of Duke Raleigh Hospital's "*FY10 Organizational Performance Improvement and Patient Safety Plan*" which documents that Duke Raleigh Hospital has an organized program of staff educations and training.

-C- **NCDI- Holly Springs-** In Section II. 8, pages 38-39, the applicant states "*All staff education and training will be provided by MedQuest Associates, Inc. MedQuest Associates Inc. has an established training program that is implemented in each of its managed facilities which includes all of the above training.*" Attachment 12 includes documentation regarding the availability of staff education and training programs.

-C- **Wake Radiology-** In Section II.8, page 57, that applicants state that they will "*continue to provide continuing education programs for Garner staff including CPR and BCLS training for appropriate clinical staff.*" Exhibit 6 contains copies of the applicants Orientation, Continuing Education Policy and CPR certification.

(e) An applicant proposing to acquire a mobile MRI scanner shall document that the requirements in Paragraph (a) of this Rule shall be met at each host facility, and that one full time MRI technologist-radiographer shall be present at each host facility during all hours of operation of the proposed mobile MRI scanner.

-NA- **None of the applicants** propose to acquire a mobile MRI scanner.

(f) An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, also shall provide:

(1) evidence that at least one licensed physician shall be on-site during the hours of operation of the proposed MRI scanner;

(2) a description of a research group for the project including a radiologist, orthopaedic surgeon, and research coordinator; and

(3) letters from the proposed members of the research group indicating their qualifications, experience and willingness to participate on the research team.

-NA- **None of the applicants** propose to acquire an extremity MRI scanner.

(g) An applicant proposing to perform cardiac MRI procedures shall provide documentation of the availability of a radiologist, certified by the American Board of Radiology, with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies.

-NA- **Duke Raleigh**- In Section II.8, page 26, the applicant states that "*This application does not propose the provision of cardiac MRI services.*"

-NA- **NCDI- Holly Springs**- In Section II.8, page 39, the applicant states that "*NCDI-Holly Springs does not anticipate performing cardiac MRI procedures.*"

-C- **Wake Radiology**- In Section II.8, page 58, the applicant states "*Dr. Coates, the MRI Medical Director for the proposed project, is certified by the American Board of Radiology, with training and experience in interpreting images produced by an MRI scanner configured to perform cardiac MRI studies.*" Exhibit 3 contains a copy of the curriculum vitae of Dr. Coates which documents that he is a board-certified radiologist with the training and experience required by this Rule.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2010 State Medical Facilities Plan, no more than one additional fixed MRI scanner may be approved in this review for Wake County. Because the three applications in this review collectively propose to acquire three additional fixed MRI scanners, only one of the applications can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Duke University Health System d/b/a Duke Raleigh Hospital, Project I.D. #J-8529-10, is approved and the two other applications are denied.

Geographic Distribution

The 2010 SMFP identifies the need for one fixed MRI scanner in Wake County. The following table identifies the location of the existing and approved fixed MRI scanners in Wake County.

Facility	City/Town	# of Existing and Approved Fixed MRI Units
Wake Radiology- Cary (Alliance)	Cary	1
Rex Healthcare of Cary	Cary	1
WakeMed Cary Hospital	Cary	1
WakeMed Raleigh Hospital	Raleigh	2
Raleigh MRI Center (Wake Radiology)	Raleigh	2
Duke Health Raleigh Hospital	Raleigh	1
Raleigh Neurology	Raleigh	1
Raleigh Radiology Cedarhurst (Pinnacle)	Raleigh	1
Raleigh Radiology (Alliance)	Raleigh	1
Rex Hospital	Raleigh	2
Total		**13**

As shown in the table above, there are 13 existing and approved fixed MRI scanners located in Wake County. Ten are located in Raleigh and three are located in Cary. There are no fixed MRI scanners located in Garner or Holly Springs.

Duke Raleigh proposes to locate an additional fixed MRI scanner at Duke Health Raleigh Hospital in Raleigh; NCDI-Holly Springs proposes to locate a fixed MRI scanner in Holly Springs; and Wake Radiology proposes to locate a fixed MRI scanner in Garner. Thus, with respect to geographic distribution, the proposals submitted by NCDI-Holly Springs and Wake Radiology are the more effective alternatives.

Demonstration of Need

Duke Raleigh adequately demonstrated that projected utilization of the existing and proposed MRI scanners is based on reasonable and supported assumptions. Therefore, Duke Raleigh adequately demonstrated the need the population it projects to serve has for the proposed fixed MRI scanner. See Criterion (3) for discussion. However, neither NCDI-Holly Springs nor Wake Radiology adequately

demonstrated that projected utilization of the respective proposed fixed MRI scanner is based on reasonable and supported assumptions. Therefore, neither NCDI-Holly Springs nor Wake Radiology adequately demonstrated the need the respective populations they projected to serve had for the proposed MRI scanner. See Criterion (3) for discussion. Therefore, the proposal submitted by Duke Raleigh is the more effective alternative with regard to demonstration of need.

Access by Underserved Groups

The applicants provided the following information regarding the percentage of their respective MRI patients projected to be Medicaid and Medicare recipients in Project Year 2, as stated by the applicants in Section VI.15 of the respective applications.

Applicant	Percentage of Total Procedures to be Provided to Medicaid Recipients	Percentage of Total Procedures to be Provided to Medicare Recipients
Duke Raleigh	8.6%	42.2%
NCDI- Holly Springs	4.8%	15.2%
Wake Radiology	2.7%	26.4%

The percentages for Duke Raleigh are based on its historic payor mix for MRI services currently provided at its existing facility. The percentages for NCDI- Holly Springs are based on the historical payor mix for MedQuest sites in the region. The percentages for Wake Radiology are based on its historic payor mix for mobile MRI services currently provided at its existing facility. As illustrated in the table above, Duke Raleigh proposes to serve the highest percentage of both Medicaid and Medicare recipients. NCDI-Holly Springs proposes to serve the lowest percentage of Medicare recipients. Wake Radiology proposes to serve the lowest percentage of Medicaid recipients. See Criterion (13c) for additional discussion. Therefore, the proposal submitted by Duke Raleigh is the more effective alternative with regard to access by Medicaid and Medicare recipients.

Revenues

The third full fiscal year of operation (Project Year 3) for Duke Raleigh is July 1, 2013 to June 30, 2014. Project Year 3 for NCDI-Holly Springs is January 1, 2014 to December 31, 2014. Project Year 3 for Wake Radiology is October 1, 2013 to September 30, 2014.

Gross revenue projections for Duke Raleigh do not include professional fees (i.e. charges for interpretation of the images by a radiologist). Gross revenue projections for both NCDI-Holly Springs and Wake Radiology do include professional fees. Neither NCDI-Holly Springs nor Wake Radiology provided the total dollar amount to be charged for professional fees or the weighted average professional fee component. Rather, in response to a rule, they provide the dollar amount charged for the professional fee component for each of the 20 procedures performed most often. The analyst used the cost of obtaining professional interpretation services as a proxy for the total gross revenue attributed to professional fees which could be greater than the cost. If the gross revenue attributed to professional fees was greater than the cost, the average gross revenue (less professional fee component) per procedure would be lower.

The average gross revenue per procedure during Project Year 3 was calculated by dividing total gross revenue by total unweighted MRI procedures. Gross revenue is from Form C and projected

unweighted MRI procedures are from Form D and Sections III and IV of the respective applications. See the following table.

Project Year 3
Average Gross Revenue per Unweighted MRI procedure

Applicant	Total Gross Revenue	# of Unweighted MRI Procedures	Average Gross Revenue per Procedure	Professional Fees*	Gross Revenue less Professional Fees	Average Gross Revenue (less Professional Fee Component) per Procedure
Duke Raleigh	$23,258,028	8,034	$2,894.95	-na-	-na-	$2,894.95
NCDI-Holly Springs	$9,537,224	4,661	$2,046.18	$387,148	$9,150,076	$1,963.11
Wake Radiology	$9,648,264	4,444	$2,171.08	$1,243,102	$8,405,162	$1,891.35

* These dollar amounts represent the cost of having a radiologist read and interpret the MRI images.

As shown in the table above, Wake Radiology projects the lowest average gross revenue (less professional fee component) per unweighted MRI procedure and NCDI-Holly Springs projects the second lowest gross revenue (less professional fee component) per unweighted MRI procedure. However, neither NCDI-Holly Springs nor Wake Radiology adequately demonstrated that projected revenues are based on reasonable and supported assumptions regarding projected utilization. See Criteria (3) and (5) for discussion. Therefore, the average gross revenue (less professional fee component) per procedure for Wake Radiology and NCDI-Holly Springs is also questionable. Duke Raleigh serves both inpatients and outpatients while NCDI-Holly Springs and Wake Radiology would serve only outpatients. Duke Raleigh also serves patients with a higher acuity than the outpatients to be served by either NCDI-Holly Springs or Wake Radiology. Thus, a higher average gross revenue per procedure is to be expected for Duke Raleigh.

Net revenue is from Form C. Duke Raleigh does not deduct either charity care or bad debt from gross revenue. NCDI-Raleigh deducts both charity care and bad debt from gross revenue. Wake Radiology deducts charity care from gross revenue but not bad debt. Wake Radiology includes bad debt as an operating cost. The following table shows the average net revenue per unweighted MRI procedure before and after deducting professional fees (NCDI-Holly Springs and Wake Radiology) and bad debt (Wake Radiology) for Project Year 3 for each applicant.

Project Year 3
Average Net Revenue per Unweighted MRI Procedure

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per Procedure	Professional Fees and Bad Debt	Net Revenue Less Professional Fees and Bad Debt	Average Net Revenue (Less Professional Fee Component) Per Procedure
Duke Raleigh	$6,923,205	8,034	$861.74	-na-	-na-	$861.74
NCDI-Holly Springs	$2,765,341	4,661	$593.29	$387,148	$2,378,193	$510.23
Wake Radiology	$4,887,124	4,444	$1,099.71	$1,759,385	$3,127,739	$703.81

As shown in the table above, NCDI-Holly Springs projects the lowest average net revenue (less professional fee component) per unweighted MRI procedure and Wake Radiology projects the second lowest average net revenue (less professional fee component) per unweighted MRI procedure. However, neither NCDI-Holly Springs nor Wake Radiology adequately demonstrated that projected revenues are based on reasonable and supported assumptions regarding projected utilization. See Criteria (3) and (5) for discussion. Therefore, the average net revenue (less professional fee component) per procedure for NCDI-Holly Springs and Wake Radiology is also questionable. Duke Raleigh serves both inpatients and outpatients while NCDI-Holly Springs and Wake Radiology would serve only outpatients. Duke Raleigh also serves patients with a higher acuity than the outpatients to be served by either NCDI-Holly Springs or Wake Radiology. Thus, higher average charges are to be expected for Duke Raleigh.

Operating Costs

Duke Raleigh's charges do not include a professional fee component, and thus, Duke Raleigh does not report any professional fee expense in Form C. NCDI-Holly Springs and Wake Radiology both state that their charges include a professional fee component. The average operating cost per procedure for Project Year 3 was calculated by dividing total operating expenses (less professional fee expense) by total unweighted MRI procedures.

Project Year 3
Average Operating Cost per Unweighted Procedure

Applicant	# of Unweighted MRI Procedures	Total Operating Costs	Professional Fees and Bad Debt	Total Operating Cost less Professional Fee Expenses and Bad Debt	Average Cost Per Procedure (less Professional Fee Component per procedure)
Duke Raleigh	8,034	$2,071,847	-na-	$2,071,847	$257.88
NCDI- Holly Springs	4,661	$1,875,820	$387,148	$1,488,672	$319.39
Wake Radiology	4,444	$2,884,476	$1,759,385	$1,125,091	$253.17

As shown in the table above, Duke Raleigh and Wake Radiology project the lowest average operating cost (less professional fee component) per unweighted MRI procedure. However, Wake Radiology did not adequately demonstrate that projected operating costs are based on reasonable and supported assumptions regarding projected utilization. See Criteria (3) and (5) for discussion. Therefore, the average operating cost (less professional fee component) per unweighted MRI procedure for Wake Radiology is also questionable. Furthermore, NCDI-Holly Springs did not adequately demonstrate that projected operating costs are based on reasonable and supported assumptions regarding projected utilization. See Criteria (3) and (5) for discussion.

SUMMARY

The following is a summary of the reasons the application submitted by **Duke Raleigh** is determined to be the most effective alternative in this review:

Duke Raleigh

- adequately demonstrates the need the population to be served has for the proposed fixed MRI scanner. See Criterion (3) for discussion.
- adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See Criterion (5) for discussion.
- proposes the highest percentage of total procedures to be provided to Medicaid and Medicare recipients. See Comparative Analysis for discussion.

The following is a summary of the reasons the applications submitted by **NCDI-Holly Springs** is found to be a less effective alternative than the application submitted by Duke University Health System d/b/a Duke Raleigh Hospital.

NCDI-Holly Springs

- did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. See Comparative Analysis for discussion.
- did not adequately demonstrate that the financial feasibility of the proposed project is based upon reasonable projections of costs and charges. See Criterion (5) for discussion.
- proposes a lower percentage of total procedures to be provided to Medicaid and Medicare recipients. See Comparative Analysis for discussion.

The following is a summary of the reasons the applications submitted by **Wake Radiology** is found to be a less effective alternative than the application submitted by Duke University Health System d/b/a Duke Raleigh Hospital.

Wake Radiology

- did not adequately demonstrate the need the population to be served has for the proposed fixed MRI scanner. See Comparative Analysis for discussion.
- did not adequately demonstrate that the financial feasibility of the proposed project is based upon reasonable projections of costs and charges. See Criterion (5) for discussion.

- proposes a lower percentage of total procedures to be provided to Medicaid and Medicare recipients. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the CON Section. The CON Section determined that the application submitted by **Duke University Health System d/b/a Duke Raleigh Hospital** is the most effective alternative proposed in this review for an additional fixed MRI scanner for Wake County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2010 SMFP and therefore, the applications submitted by **North State Imaging, LLC d/b/a North Carolina Diagnostic Imaging- Holly Springs** and **Wake Radiology Diagnostic Imaging, Inc. and Wake Radiology Services, LLC** are denied.

The application submitted by Duke University Health System d/b/a Duke Raleigh Hospital is approved subject to the following conditions.

1. **Duke University Health System d/b/a Duke Raleigh Hospital shall materially comply with all representations made in its certificate of need application.**

2. **Duke University Health System d/b/a Duke Raleigh Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

3. **Duke University Health System d/b/a Duke Raleigh Hospital shall acquire no more than one fixed MRI scanner for a total of no more than two fixed MRI scanners.**

4. **Duke University Health System d/b/a Duke Raleigh Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

EXHIBIT

C

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DATE: February 5, 2010
PROJECT ANALYST: Les Brown
TEAM LEADER: Martha J. Frisone

PROJECT I.D. NUMBER: A-8430-09 / Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC / Relocate one existing ambulatory surgical facility with one licensed gastrointestinal endoscopy room from its present location at 2730 Georgia Road to 211 Riverview Street in Franklin / Macon 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

Western Carolina Endoscopy Center, LLC (WCEC) (Lessee) and Western Carolina Medical Developers, LLC (WCMD) (Lessor) propose to relocate an existing ambulatory surgical facility with one licensed gastrointestinal (GI) endoscopy procedure room from its current location in a medical office building at 2730 Georgia Road to another medical office building at 211 Riverview Street in Franklin. The offices of the related gastroenterology medical practice, Western Carolina Digestive Consultants, PA, will be relocated to space adjoining the ambulatory surgical facility. There are no policies or need determinations in the 2009 State Medical Facilities Plan applicable to the review of this application. Therefore, this criterion is not applicable in 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.

C

WCEC and WCMD propose to relocate an existing ambulatory surgical facility with one licensed GI endoscopy procedure room from the existing medical office building on Georgia Road to another medical office building on Riverview Street in Franklin. The relocated ambulatory surgical facility will occupy 4,526 square feet of space on the third floor of the building, which will contain a total of 25,460 square feet of space. WCEC will lease the space from WCMD.

Population to be Served

In Section III.6, page 19, the applicants state that the service area for the existing GI endoscopy procedure room is Macon, Jackson, Cherokee, Swain and Graham Counties, and provide projected patient origin for the first two years of operation, as illustrated in the following table.

Projected Patient Origin – Years 1 & 2

County	% of Patients
Macon	47.0%
Jackson	35.0%
Cherokee	7.0%
Swain	6.0%
Graham	2.0%
All Other	3.0%
Total	100.0%

In Section III.7, page 20, the applicants provide the current patient origin, which was used by the applicants as a basis for the projected patient origin, as illustrated in the following table.

Current Patient Origin

County	% of Patients
Macon	45.0%
Jackson	35.0%
Cherokee	7.0%
Swain	6.0%
Graham	2.0%
All Other*	4.5%
Total**	99.5%

* "All other" includes Haywood, Buncombe and Henderson Counties, Georgia and other states.
** Does not equal 100% due to rounding.

The applicants adequately identify the population proposed to be served.

Need for the Proposed Service

Regarding the need to relocate the existing ambulatory surgical facility to another location in Franklin, in Section III.1, page 15, the applicants state:

> *"Our current location is 1800 square feet of leased space. We are limited by physical space and are only able to provide one service at a time. We stop the Endoscopy schedule by 2:00 pm in order to allow time for office visits. Due to limited office visit availability our current wait for an office visit is an average of 9 weeks in our Franklin location. We are offering patients an appointment in our Sylva office (Jackson County) to expedite their consultation. Our current wait time for an appointment in the Sylva office is 6 weeks."*

In Section III.9, page 21, the applicants state:

> *"The current location is physically inadequate. The new facility will provide faster access to office consultations as our scheduling block time now for consultations is extremely limited in Franklin. Majority of our patients are currently driving to Sylva for their office consults. There will be a physical distinct separation of Western Carolina Digestive Consultants, PA for the practice from Western Carolina Endoscopy Center, LLC for procedures. The current location has a shared waiting room that is very small with limited privacy. The new location will be 5 miles closer to the center of town and more conveniently located. The physicians will own the building."*

In Section III.8, page 20, the applicants state:

"The option of adding to our existing leased space was considered. The tenant next to us is under a 3 year lease and plans to stay on the property long term. Our current location is at the end of the building and borders parking lot and property line. After these options were considered, the most effective solution is to be more centrally located in town and near other medical facilities. The new location is located in what is considered the "medical park" of Franklin. The physicians would also like to own their own property vs. leasing. In the new facility there will be separate office space from Endoscopy. We will then be able to see office patients 5 days/week in Franklin and patients would not be asked to drive to our Sylva office for their office visit. The Endoscopy schedule will also be able to run 5 days/week."

The applicants adequately demonstrate the need to relocate the existing ambulatory surgical facility to a larger space.

On page 22, the applicants provide the following historical and projected utilization:

Historical and Projected Utilization

	CY 2007	CY 2008	1/1/2009-8/31/09	Year 1 5/1/2010 – 4/30/2011	Year 1 5/1/2010 – 4/30/2011	Year 1 5/1/2010 – 4/30/2011
GI Endoscopy Procedures	1,511	1,545	1,061	1,680	1,764	1,852

The applicants propose to increase the hours of operation from 26 hours per week to 47.5 hours per week after completion of the project, allowing for increased capability to perform more procedures. In Section III.1, page 15, the applicants state: *"Our current wait for an office visit is an average of 9 weeks in our Franklin location. ...Our current wait time for an appointment in the Sylva office is 6 weeks."* The applicants are currently performing over 1,500 GI endoscopy procedures per year, which exceeds the 1,500 procedures required by 10A NCAC 14C .3903(b). The applicants adequately demonstrate projected utilization is based on reasonable and supported assumptions.

The applicants adequately demonstrate the need the population to be served has for the proposed project. Consequently, the application is conforming 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.

C

The applicants propose to relocate the existing ambulatory surgical facility with one licensed GI endoscopy procedure room from a medical office building in Franklin to another medical office building in Franklin, approximately 7 miles away. The new facility would be more centrally located near Angel Medical Center and other physician office practices. The proposed patient origin is similar to the current patient origin. The applicants adequately demonstrate that the needs of the population presently served by WCEC would be met adequately following the proposed relocation of the ambulatory surgical facility. Consequently, the application is conforming with 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.

CA

In Section III.8, page 20, the applicants discuss the alternatives considered prior to submission of this application and the basis for selection of the proposed project. Furthermore, the application is conforming with all applicable statutory review criteria. See Criteria (3), (5), (6), (7), (8), (12), (13), (14), (18a) and (20). Therefore, the applicants adequately demonstrate that the proposed project is their least costly or most effective alternative, and the application is conforming with this criterion subject to the following conditions:

1. **Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC shall relocate the existing ambulatory surgical facility with one licensed gastrointestinal endoscopy room to a new location in Franklin which shall not be licensed for more than one gastrointestinal endoscopy room in the new location.**

3. **The facility fee charged per procedure by Western Carolina Endoscopy Center, LLC shall be no more than $1,011 in**

operating year one, $1,204 in operating year two and $1,376 in operating year three.

4. **Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC shall prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.**

5. **Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

(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.

CA

In Section VIII.1, page 42, the applicants project that the total capital cost will be $2,210,090, including $295,000 for land acquisition, $256,810 for site preparation, $1,423,780 for construction costs and $234,500 for miscellaneous costs. However, the actual miscellaneous costs in the application amount to $412,275 because the applicant failed to include the *"Other Builders Fee"* of $177,775 ($234,500 + $177,775 = $412,275). The applicants also include $295,000 for the purchase price of the land. However, the applicants state the land was purchased in March, 2007 and thus, should not be included in the projected capital costs. The total capital cost for the project, which includes the cost of the entire medical office building, not just the ambulatory surgical facility, is $2,092,865 ($256,810 + $1,423,780 + $234,500 + $177,775 = $2,092,865).

In Section IX.1, page 44, the applicants project that there will be no start-up or initial operating expenses.

In Section VIII.2, page 42, the applicants state that 95% of the capital cost will be financed with a conventional loan. Exhibit 10 contains a September 23, 2009 e-mail from Rob McFarland of First Citizens Bank, which states that the loan request is being reviewed by the *"credit officer."* Also in Section VIII.2, page 42, the applicants state that the remaining 5% of the capital cost would come from accumulated reserves. However, Form A Balance Sheet in

the pro forma financial statements shows that WCEC only had $29,747 in cash and cash equivalents as of August 31, 2009.

In Form D the applicants state that the average facility charge per procedure during the first three operating years will be $1,011 in Year 1, $1,204 in Year 2 and $1,376 in Year 3. In Form B the applicants project that revenues will exceed operating costs in each of the first three operating years. The assumptions used by the applicants in preparation of the pro formas are reasonable, including projected utilization, costs and charges. See Criterion (3) for discussion of utilization projections. Therefore, the applicants adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues, and the application is conforming with this criterion subject to the following conditions:

1. **The total capital cost for the project shall be $2,092,865, which includes the cost of construction for the entire physician office building.**

2. **Prior to issuance of the certificate of need, Western Carolina Endoscopy Center, LLC and Western Carolina Medical Developers, LLC shall provide the Certificate of Need Section with documentation of funding for the total capital expenditure.**

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

C

The applicants adequately demonstrate the need to relocate the existing ambulatory surgical facility with one licensed GI endoscopy room from Georgia Road to Riverview Street in Franklin. See Criterion (3) for discussion. Consequently, the applicants adequately demonstrate that the proposal would not result in unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming 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

The following table illustrates current and projected staffing at WCEC during the second operating year, as reported by the applicants in Sections VII.1 and VII.2, pages 34-35.

POSITION	# OF FULL TIME EQUIVALENT POSITIONS (FTES)	
	CURRENT	YEAR TWO
Administrator	0.75	0.75
Registered Nurses (RNs)	1.75	1.75
Nursing Aides	2.00	2.00
GI Endoscopy Technician	1.00	1.00
Total	5.50	5.50

In Section VII, page 38, the applicants state that Philip Stack, MD, gastroenterologist and managing partner, is the Medical Director of the facility. In Section VII.9, page 39, the applicants state that a total of three gastroenterologists will perform GI endoscopy procedures at the proposed facility. The applicants demonstrated the availability of adequate health manpower and management personnel for the provision of the proposed services. Therefore, the application 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.2, the applicant state:

> *"The following ancillary and support services are currently provided at our existing facility by outside vendors: Housekeeping, Linen, Biohazard/Waste, Biomedical Equipment Inspection, Pharmacy Inspection, and Maintenance.*
>
> ...
>
> *Our current letters of agreement and services will continue at the new location."*

Exhibit 7 contains letters from physicians that state their support for the proposed project and their intent to refer patients to the proposed facility. Exhibit 5 contains e-mail correspondence with Angel Medical Center requesting that a transfer agreement be arranged between WCEC and the

hospital. It also contains a letter from Macon County Emergency Services explaining the procedures for requesting emergency services when necessary.

The applicants adequately demonstrate that the necessary ancillary and support services will continue to be available and that the services would continue to be coordinated with the existing health care system. Consequently, the application is conforming with 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.

C

WCMD proposes to construct a medical office building in Franklin and lease 4,526 square feet to WCEC for the relocated ambulatory surgical facility. In Section VIII.1, page 41, the applicants project construction costs of $1,423,780 for the entire 25,460 square foot medical office building. The architect's estimate of costs for construction of the GI endoscopy suite provided in Exhibit 14 is $869,414, including the prorated cost for site development, 5% contingency and 4.6% for architectural and engineering fees. In Exhibit 13, the applicants provide a letter from the architect which describes the energy saving features which have been incorporated into the construction plans. The applicants 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. Therefore, the application is conforming with 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 payor mix for GI endoscopy services provided by WCEC during CY 2008, as reported by the applicants in Section VI.12, page 32.

PAYOR CATEGORY	PERCENT OF TOTAL
Self Pay / Indigent / Charity Care	21.1%
Commercial Insurance	45.3%
Medicare	29.6%
Managed Care	4.0%
Total	100.0%

As shown in the table above, 21.1% of WCEC's patients are self-pay, indigent or charity care. The applicants demonstrate that medically underserved populations currently have adequate access to the existing GI endoscopy services provided at WCEC and the application is conforming with 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

In Sections VI.10 and VI.11, pages 31-32, concerning civil rights complaints and government obligations for uncompensated care, the applicants state *"NA."* In Section VI.8, page 30, the applicants state that during January – August 2009, WCEC provided charity care in the amount of $120,676, or 25% of net revenue. Therefore, 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

The following table illustrates the projected payor mix for WCEC during the second operating year, as reported by the applicants in Section VI.14, page 33.

PAYOR CATEGORY	PERCENT OF TOTAL
Self Pay / Indigent / Charity Care	22.4%
Commercial Insurance	46.1%
Medicare	21.0%
Managed Care	10.5%
Total	100.0%

The applicants propose to increase the percentage of patients who are self pay, indigent or charity care by Year 2 of the project. The applicants demonstrate that medically underserved populations will have adequate access to the proposed services and therefore, 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, page 31, the applicants state that the *"facility operated by physician referral."* 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

Exhibit 4 contains a letter from Western Carolina University expressing appreciation to WCEC for allowing students in the Nursing and Nutrition Program to observe procedures at WCEC. In Section V.1, page 23, the applicants state that the new facility will allow WCEC to accommodate more students from Western Carolina University, as well as students from Southwestern Community College. Thus, WCEC currently accommodates the clinical needs of health professional training programs in the area and the applicants state that the new facility will do the same. 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.

C

The applicants adequately demonstrate that the proposal would have a positive impact on the cost effectiveness, quality and access to the services proposed. See Criteria (3), (3a), (5), (7), (8), (12), (13) and (20) for discussion. Therefore, the application is conforming 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

The facility is accredited by AAAHC [Accreditation Association for Ambulatory Health Care] as an ambulatory surgery center. According to the records in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at WCEC 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 with 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 applicants are relocating an existing ambulatory surgical facility with one licensed GI endoscopy procedure room to another location and do not propose to add any new GI endoscopy procedure rooms to the facility. They are not establishing a new ambulatory surgical 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 to this review.

EXHIBIT
D

The best retirement cities June 9, 2000: 12:41 p.m. ET

Money magazine ranks the best places to have an active retirement

By staff writer Mark Gongloff NEW YORK (CNNfn) - If you're looking for a stimulating retirement spot, *Money* magazine has made the search a little easier, naming five cities with a wealth of activities for retirees.

In its July issue, *Money* named Bradenton, Fla.; Fort Collins, Colo.; Bend, Ore.; Asheville, N.C.; and Brunswick, Me., as the five best U.S. towns in which to spend your golden years.

graphic

Money found the cities where people retire most often and then picked the ones "where a vigorous retirement is the norm."

The magazine ranked cities based on availability of continuing education, outdoor and cultural activities, accessibility of medical care and transportation, cost of living, taxes and home prices.

Though many retirees prefer temperate locales like Florida or the Southwest, weather was less important to *Money* when picking its winners. Brunswick, for example, has an average low temperature of 11.7F, but *Money* likes it for its museums, theaters, and restaurants; the availability of golfing, sailing and other outdoor activities; its proximity to Boston, and the presence of Bowdoin College.

In fact, Fort Collins, Bend, Asheville and Brunswick together have an average low temperature of 20.5F. Those of us who would rather golf than shovel a driveway could live in Bradenton (average low a balmy 50.1F) or go to *Money*'s retirement-locale web site, where you can search for retirement locations that match your personal criteria for livability.

Do you like a place that's "cultured and outdoorsy at the same time," as *Money* put it? Fort Collins, Asheville or Bend may be for you. Do you want to recover from a lifetime of work by gorging on golf and baseball? Bradenton, with 24 golf courses, is where eight major-league teams hold spring training. Do you want to be far from the madding crowd? Asheville is two hours by car from the nearest big city (Charlotte), and Bend is a three-hour drive from Portland, Ore.

As *Money* writer Patricia Skalka pointed out, "There is no one formula for picking the best place to settle down." Find a place that suits you best.

Money also named five runners-up: Santa Fe, N.M.; Hot Springs, Ark.; San Luis Obispo, Calif.;

Ex. D p. 2

Madison, Wis.; and Amherst, Mass.

Click here to read more of Money's best retirement places.

Find this article at:
http://money.cnn.com/2000/06/09/senior_living/q_retire_places

☐ Check the box to include the list of links referenced in the article.

Exhibit D, p. 3

CNNMoney.com

PRINTTHIS
Powered by Clickability

Best places to retire June 14, 2000: 9:58 a.m. ET

Modern Maturity names the 50 most active places to live during retirement

By Staff Writer Jennifer Karchmer NEW YORK (CNNfn) - If you think retirement means riding ATVs on the beach, watching a Shakespeare play at night and starting your own consulting firm after saying goodbye to corporate America, then a new survey will help you find the perfect town to have it all.

Modern Maturity magazine has come out for the first time with a list of the most active places to live in the country if you're over 50 and preparing to retire.

graphic

"Retirement is coming to have a different meaning than it used to," said *Modern Maturity* senior editor Gabrielle deGroot Redford. "(Baby) Boomers are going to retire differently than their parents did."

Relaxing on the front porch of the retirement home or playing a round of golf is being replaced with world-wide traveling, rock climbing and hiking, and opening a new business, she added. It's no secret Americans are living longer and stronger.

So *Modern Maturity* judged places based on transportation, restaurants, health care, crime rates, recreational and cultural activities, and availability of continuing education and affordability. A team of researchers spent six months studying the cities to come up with the following winners: Boulder, Colo., Austin, Texas, Boston, Mass., Asheville, N.C., and Sonoma County, Calif.

Boulder, Colo.

Boulder, Colo., took the top spot in the magazine's **Green and Clean** category because of the town's abundance of outdoor and recreational activities, access to top-level health care, proximity to University of Colorado in Boulder, low crime rate, and walkability factor.

Modern Maturity named Bend, Ore., and Annapolis, Md., as runner-up cities based on fresh air and outdoor activities.

EX. D, P. 4

Austin, Texas

Maybe you've been thinking about taking a night class at the local university or a course on comparative literature?

graphic

More and more retirees are finding time to expand their knowledge and master new hobbies and skills. *Modern Maturity* named Austin, Texas, its top pick for **College Towns.**

"The city offers unique things for seniors, lifelong classes, seniors can take classes for free or a nominal fee -- woodworking to history," Redford said.

Adding to Austin's attractiveness for an older, but active crowd, is the city's progressiveness, its environmentally friendly attitude, and hiking and biking trails.

"The Baby Boomer generation is very active and aware of exercise in terms of health and longevity," Redford said.

Charlottesville, Va., home of the University of Virginia, and Columbia, Mo., home of the University of Missouri, were named as runner-up cities for college towns.

Click here to find out how Modern Maturity rates each of the cities

---

Boston, Mass.

Boston, Mass., certainly isn't the biggest city out there, but *Modern Maturity* rated it the best **Big City** for retirement, thanks to its abundance of colleges and universities and quaint neighborhoods.

"Boston has a high vitality quotient with a lot of culture, lectures, and concerts," Redford said. "It's a town of niches," home to Harvard University, Boston University, Boston College, and Emerson College, among other schools.

And it's no secret that older Americans are shying away from typical warm climates, opting for more culture and outdoor activities.

"The new generation of retirees is not necessarily going to move to Florida; either they're staying put or moving to be near family or they're moving back to where their alma mater is, but it's away from moving to the Sun Belt," she said.

Runner-up cities were San Francisco and Sarasota, Fla.

Asheville, N.C.

Ex. D, p 5

Asheville, N.C., which is two hours by car from Charlotte -- the nearest big city -- got high marks for its cultural atmosphere, orchestra, concerts and theatre, according to Redford. In addition, it's situated in the Blue Ridge Mountains.

With a population of 68,000, Asheville is considered the best **Small Town** on *Modern Maturity's* list. *Money* also chose Asheville as one of its top retirement cities.

Ashland, Ore., and Silver City, N.M., were named as runner-up cities.

Sonoma County, Calif.

Because of its unique mix of natural beauty, wineries, ranches, and progressive politics, the magazine named Sonoma County, Calif. the best **Quirky** city. Sonoma boasts organic food, a center for alternative medicine, and a low crime rate.

"Health care has always been important, but Baby Boomers may be more interested in alternative health care," Redford said. "I don't necessarily think 10 years ago people were too terribly concerned about outdoor recreation and vitality."

Key West, Fla., and Reno, Nev., are runner-up cities for the Quirky category.

"I think people are doing homework on retirement cities," Redford added.

"There are books out, places rated. They're big sellers." ■

-- Staff Writer Jennifer Karchmer covers retirement news for CNNfn.com. Click here to send her e-mail.

Find this article at:
http://money.cnn.com/2000/06/14/senior_living/q_retire_cities

☐ Check the box to include the list of links referenced in the article.

EXHIBIT
E

mapquest

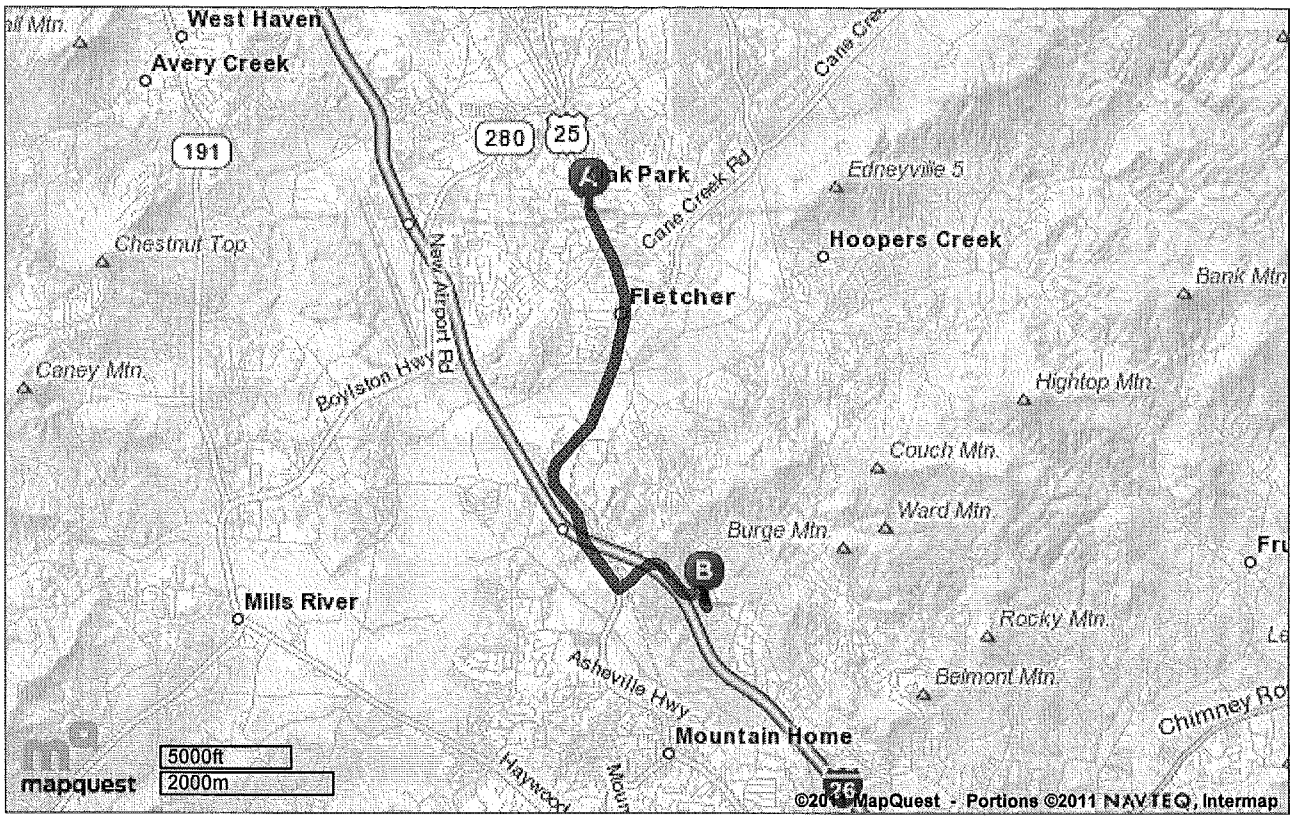
Notes

Mission GI South to Park Ridge

Trip to:
100 Hospital Dr
Hendersonville, NC 28792-5272
5.32 miles
10 minutes

A		**2651 Hendersonville Rd** Arden, NC 28704-8527	**Miles Per Section**	**Miles Driven**
●		1. Start out going SOUTH on HENDERSONVILLE RD / US-25 toward ALLIANCE PAGE RD. Continue to follow US-25 S.	**Go 3.6 Mi**	3.6 mi
↑	SOUTH 25 BR	2. US-25 S becomes ASHEVILLE HWY / US-25-BR S.	**Go 0.5 Mi**	4.1 mi
↰		3. Turn LEFT onto S NAPLES RD. *S NAPLES RD is 0.2 miles past NAPLES RD*	**Go 0.2 Mi**	4.3 mi
↱		4. Turn RIGHT onto NAPLES RD.	**Go 0.8 Mi**	5.1 mi
↱		5. Take the 2nd RIGHT onto HOSPITAL DR. *If you reach HOMESTEAD FARM CIR you've gone a little too far*	**Go 0.2 Mi**	5.3 mi
■		6. 100 HOSPITAL DR. *Your destination is 0.1 miles past DOCTORS DR*		5.3 mi
B		**100 Hospital Dr** Hendersonville, NC 28792-5272	**5.3 mi**	**5.3 mi**

Total Travel Estimate: **5.32 miles - about 10 minutes**



EXHIBIT

F

mapquest

Trip to:
1032 Fleming St
Hendersonville, NC 28791-3532
9.82 miles
18 minutes

Notes

Mission GI South to Carolina Mountain Endoscopy

A	**2651 Hendersonville Rd** Arden, NC 28704-8527	**Miles Per Section**	**Miles Driven**
●	1. Start out going SOUTH on HENDERSONVILLE RD / US-25 toward ALLIANCE PAGE RD. Continue to follow US-25 S.	**Go 3.6 Mi**	3.6 mi
↑	2. US-25 S becomes ASHEVILLE HWY / US-25-BR S.	**Go 6.2 Mi**	9.7 mi
↱	3. Turn RIGHT onto FLEMING ST. *If you reach OAKLAND ST you've gone a little too far*	**Go 0.09 Mi**	9.8 mi
■	4. 1032 FLEMING ST is on the LEFT. *Your destination is just past SHIPP ST* *If you reach PATTON ST you've gone a little too far*		9.8 mi
B	**1032 Fleming St** Hendersonville, NC 28791-3532	**9.8 mi**	**9.8 mi**

Total Travel Estimate: **9.82 miles - about 18 minutes**

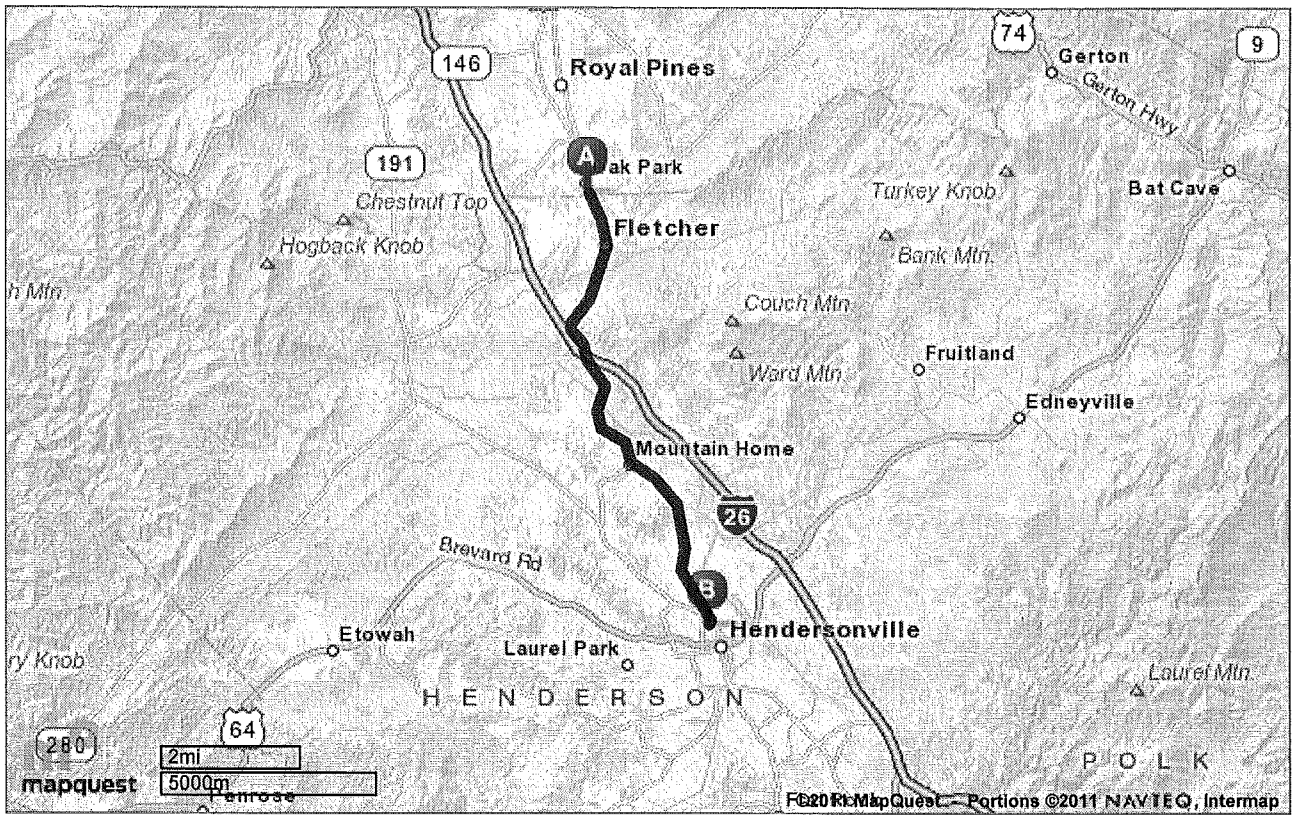


EXHIBIT G

mapquest

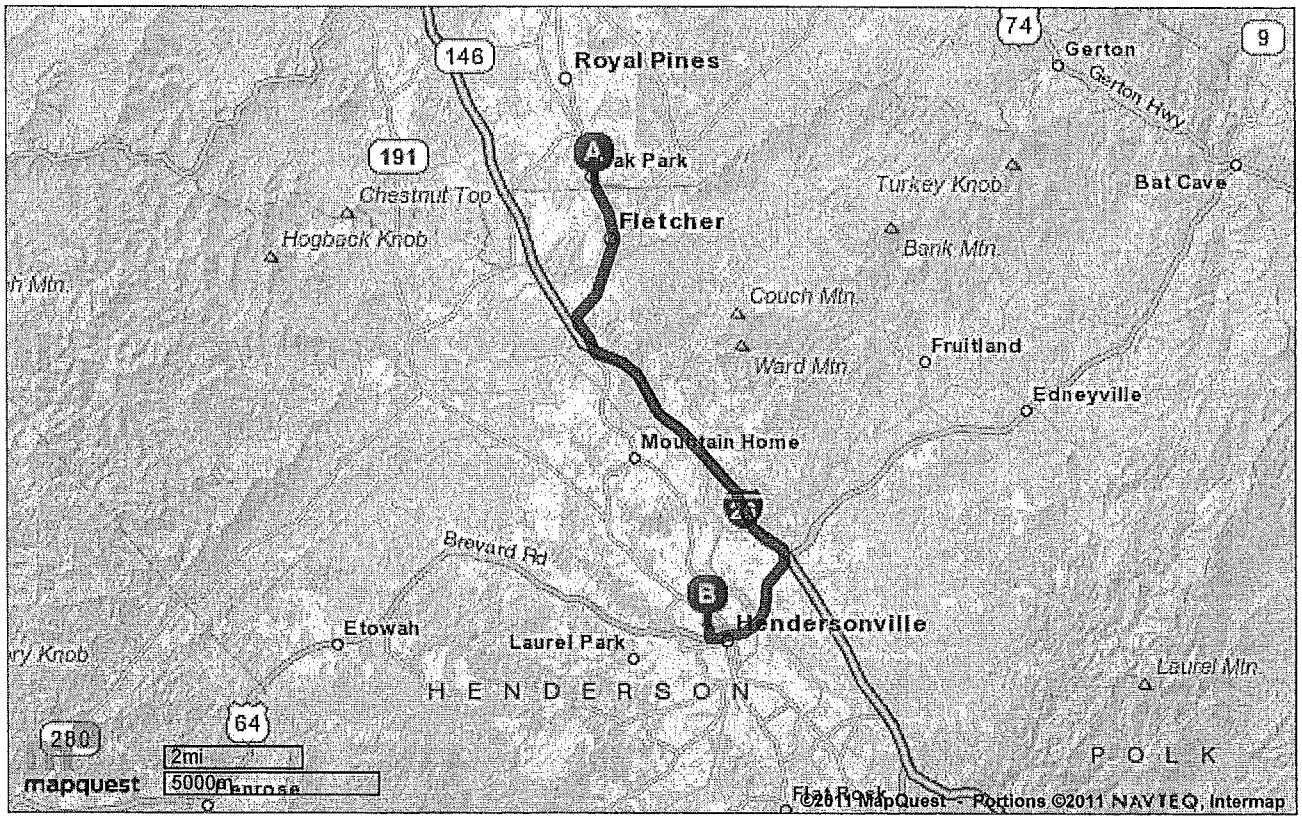
Notes

Mission GI Sutts to Pardee

Trip to:
800 N Justice St
Hendersonville, NC 28791-3410
11.84 miles
18 minutes

		Miles Per Section	Miles Driven
A	**2651 Hendersonville Rd** Arden, NC 28704-8527		
●	1. Start out going SOUTH on HENDERSONVILLE RD / US-25 toward ALLIANCE PAGE RD. Continue to follow US-25 S.	**Go 3.6 Mi**	3.6 mi
↑ EXIT 25	2. Merge onto I-26 E / US-25 S / US-74 E via the ramp on the LEFT. *If you reach S CURETON PL you've gone about 0.1 miles too far*	**Go 5.5 Mi**	9.0 mi
49B EXIT ↗ WEST 64	3. Merge onto US-64 W via EXIT 49B toward HENDERSONVILLE.	**Go 2.4 Mi**	11.4 mi
← WEST 64	4. Turn LEFT onto BUNCOMBE ST / US-64 W.	**Go 0.04 Mi**	11.5 mi
→ 64	5. Take the 1st RIGHT onto 6TH AVE W / US-64. *If you reach 5TH AVE W you've gone about 0.1 miles too far*	**Go 0.3 Mi**	11.7 mi
→	6. Take the 3rd RIGHT onto N JUSTICE ST. *If you reach N OAK ST you've gone about 0.1 miles too far*	**Go 0.1 Mi**	11.8 mi
■	7. 800 N JUSTICE ST is on the RIGHT. *If you reach CONNOR AVE you've gone a little too far*		11.8 mi
B	**800 N Justice St** Hendersonville, NC 28791-3410	**11.8 mi**	**11.8 mi**

Total Travel Estimate: **11.84 miles - about 18 minutes**



EXHIBIT

H

mapquest

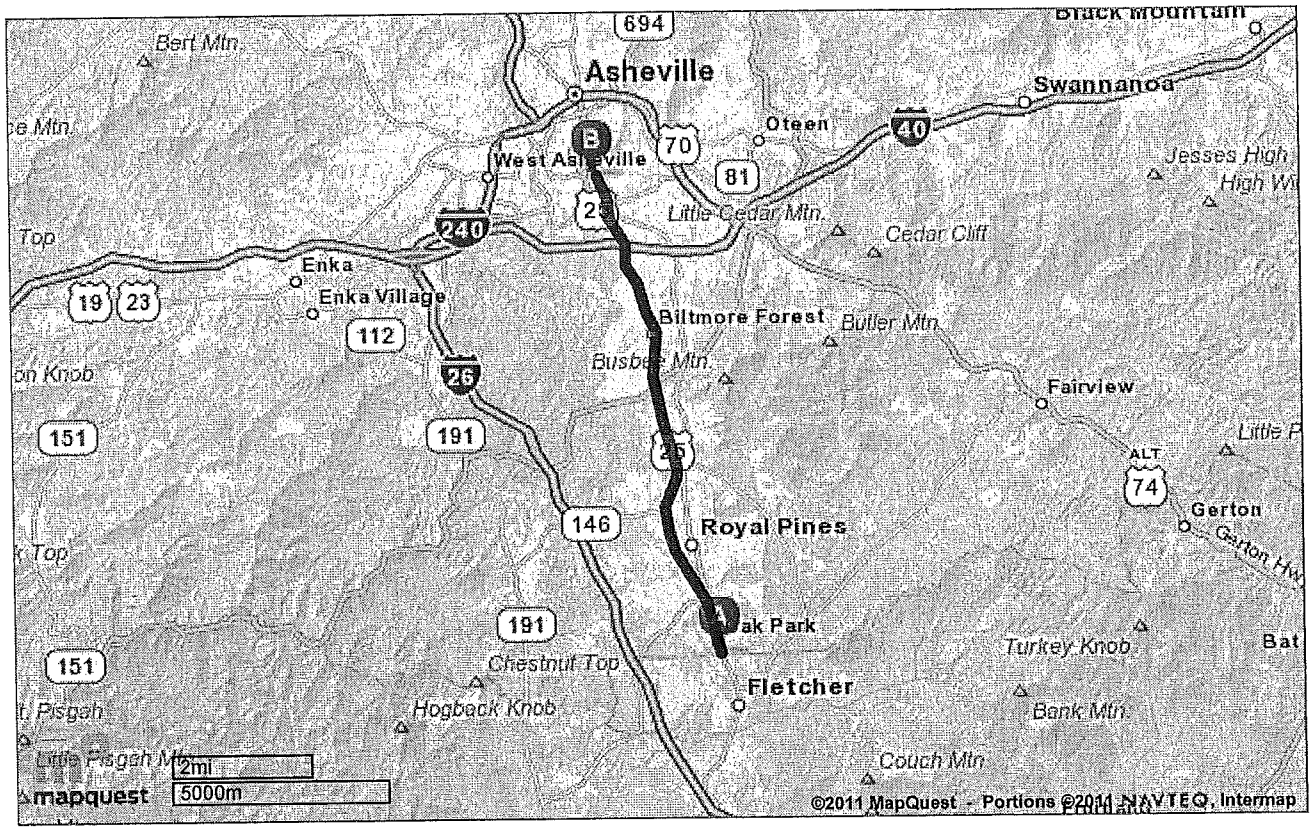
Notes

Mission GI
South to Mission

Trip to:
509 Biltmore Ave
Asheville, NC 28801-4601
9.93 miles
16 minutes

		Miles Per Section	Miles Driven
A	**2651 Hendersonville Rd** Arden, NC 28704-8527		
●	1. Start out going NORTH on HENDERSONVILLE RD / US-25 toward SHARP SOLUTIONS DR. Continue to follow US-25.	**Go 9.1 Mi**	9.1 mi
↱ 25 ALT	2. Turn RIGHT onto US-25-ALT. *US-25-ALT is just past BOSTON WAY*	**Go 0.04 Mi**	9.1 mi
↰	3. Take the 1st LEFT onto BILTMORE AVE. *If you reach BILTMORE PLZ you've gone a little too far*	**Go 0.8 Mi**	9.9 mi
■	4. 509 BILTMORE AVE is on the LEFT. *Your destination is just past FOREST HILL DR* *If you reach GRANBY ST you've gone a little too far*		9.9 mi
B	**509 Biltmore Ave** Asheville, NC 28801-4601	**9.9 mi**	**9.9 mi**

Total Travel Estimate: **9.93 miles - about 16 minutes**



EXHIBIT

I

mapquest

Notes

Mission GI South
to Asheville Gastro –
The Endoscopy Center

Trip to:
191 Biltmore Ave
Asheville, NC 28801-4109
10.90 miles
17 minutes

	Directions	Miles Per Section	Miles Driven
A	**2651 Hendersonville Rd** Arden, NC 28704-8527		
●	1. Start out going NORTH on HENDERSONVILLE RD / US-25 toward SHARP SOLUTIONS DR. Continue to follow US-25.	**Go 10.5 Mi**	10.5 mi
↱ 25	2. Turn SLIGHT RIGHT onto SOUTHSIDE AVE / US-25. *SOUTHSIDE AVE is 0.1 miles past CHOCTAW ST*	**Go 0.4 Mi**	10.9 mi
↰ 25	3. Turn LEFT onto BILTMORE AVE / US-25. *BILTMORE AVE is just past S LEXINGTON AVE*	**Go 0.01 Mi**	10.9 mi
■	4. 191 BILTMORE AVE is on the LEFT. *If you reach CARROLL AVE you've gone a little too far*		10.9 mi
B	**191 Biltmore Ave** Asheville, NC 28801-4109	**10.9 mi**	**10.9 mi**

Total Travel Estimate: **10.90 miles - about 17 minutes**

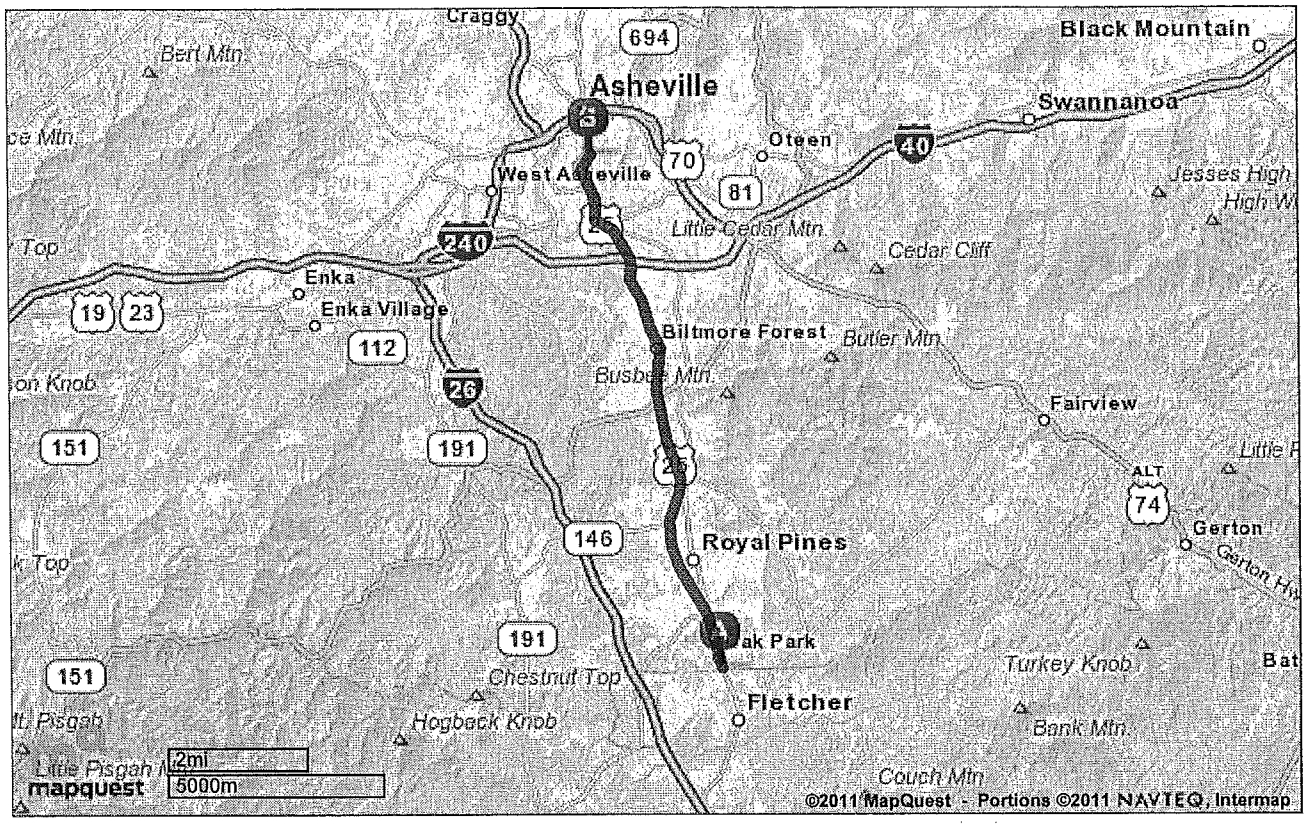


EXHIBIT
J

United States Department of Agriculture
Economic Research Service
The Economics of Food, Farming, Natural Resources, and Rural America

Data Sets

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- Research & Productivity
- Rural Economy
- Trade & International Markets

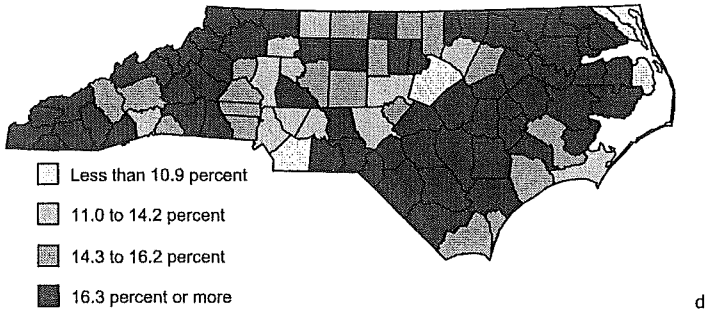
2009 County-Level Poverty Rates for North Carolina

North Carolina go

Percent **Number**

Go to the map to select a State
Go to North Carolina State Fact Sheet

Percent of total population in poverty, 2009



d

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Click a column name to sort the table by that column.

				All people in poverty (2009)			Children ages 0-17 in poverty (2009)		
					90% confidence interval of estimate			90% confidence interval of estimate	
	FIPS*	Name	RUC Code[1]	Percent	Lower bound	Upper bound	Percent	Lower bound	Upper bound
1	37000	North Carolina		16.2	16.0	16.5	22.5	21.9	23.0
2	37001	Alamance County	3	15.2	13.2	17.2	20.1	16.2	23.9
3	37003	Alexander County	2	14.9	12.1	17.7	22.1	17.5	26.7
4	37005	Alleghany County	9	19.3	14.8	23.9	31.5	24.5	38.6
5	37007	Anson County	1	24.1	18.9	29.4	32.1	25.1	39.1
6	37009	Ashe County	9	18.1	14.7	21.6	26.4	20.4	32.4
7	37011	Avery County	8	18.9	14.5	23.2	27.3	21.1	33.4
8	37013	Beaufort County	6	19.3	16.0	22.6	31.2	25.9	36.5
9	37015	Bertie County	9	24.3	18.9	29.7	34.9	27.2	42.6

10	37017	Bladen County	6	23.3	19.4	27.2	30.5	24.7	36.3
11	37019	Brunswick County	2	14.6	12.1	17.2	26.0	20.6	31.3
12	37021	Buncombe County	2	16.2	14.0	18.4	22.4	18.6	26.2
13	37023	Burke County	2	17.4	14.7	20.1	23.5	18.8	28.2
14	37025	Cabarrus County	1	11.4	9.8	13.0	16.4	13.6	19.1
15	37027	Caldwell County	2	16.7	14.1	19.3	25.2	20.4	30.1
16	37029	Camden County	8	8.9	6.8	11.0	12.8	10.0	15.7
17	37031	Carteret County	4	13.1	10.4	15.8	22.5	17.7	27.3
18	37033	Caswell County	8	22.6	19.2	26.0	27.8	22.4	33.2
19	37035	Catawba County	2	14.4	12.6	16.2	20.9	17.5	24.3
20	37037	Chatham County	2	11.0	8.7	13.2	17.6	13.9	21.3
21	37039	Cherokee County	9	17.8	13.6	21.9	31.5	24.4	38.7
22	37041	Chowan County	7	20.6	16.3	24.8	31.3	24.6	38.0
23	37043	Clay County	9	16.9	13.0	20.7	28.7	22.3	35.2
24	37045	Cleveland County	4	17.5	14.8	20.3	25.9	21.1	30.8
25	37047	Columbus County	6	25.4	21.7	29.0	38.2	33.0	43.4
26	37049	Craven County	5	16.1	14.0	18.2	25.7	21.8	29.7
27	37051	Cumberland County	2	17.0	15.0	19.0	24.4	20.5	28.3
28	37053	Currituck County	1	10.4	7.8	12.9	17.4	13.4	21.4
29	37055	Dare County	5	10.7	8.4	13.0	17.9	14.0	21.9
30	37057	Davidson County	4	14.6	12.6	16.6	22.4	18.7	26.0
31	37059	Davie County	2	11.7	9.4	14.0	17.9	14.5	21.3
32	37061	Duplin County	6	24.3	21.3	27.2	33.0	28.0	38.1
33	37063	Durham County	2	16.4	14.6	18.2	22.5	19.1	25.8
34	37065	Edgecombe County	3	25.7	22.0	29.3	34.8	28.6	41.0
35	37067	Forsyth County	2	16.5	15.0	18.0	23.6	20.8	26.3

36	37069	Franklin County	2	13.7	10.6	16.7	19.9	15.4	24.3
37	37071	Gaston County	1	15.6	13.5	17.6	21.7	18.1	25.4
38	37073	Gates County	8	17.5	14.1	21.0	24.1	19.2	28.9
39	37075	Graham County	9	19.6	14.8	24.4	33.9	26.3	41.5
40	37077	Granville County	6	14.8	11.9	17.6	18.5	14.7	22.4
41	37079	Greene County	3	23.0	17.8	28.3	31.4	24.7	38.1
42	37081	Guilford County	2	17.1	15.3	18.8	22.1	19.4	24.7
43	37083	Halifax County	4	26.8	23.1	30.6	35.6	29.3	42.0
44	37085	Harnett County	4	17.3	14.5	20.1	23.4	19.2	27.6
45	37087	Haywood County	2	15.2	12.4	18.1	24.9	19.6	30.3
46	37089	Henderson County	2	12.4	10.0	14.7	21.0	16.9	25.1
47	37091	Hertford County	7	24.9	20.0	29.8	34.6	27.7	41.5
48	37093	Hoke County	2	21.3	18.0	24.6	30.1	25.2	34.9
49	37095	Hyde County	9	24.0	18.6	29.5	29.6	23.0	36.3
50	37097	Iredell County	4	13.1	11.6	14.6	17.9	15.3	20.5
51	37099	Jackson County	6	20.5	16.7	24.3	26.3	20.6	32.0
52	37101	Johnston County	2	17.4	15.6	19.2	23.4	20.6	26.3
53	37103	Jones County	8	18.3	14.1	22.6	29.7	23.0	36.4
54	37105	Lee County	4	14.5	11.7	17.3	22.1	17.4	26.8
55	37107	Lenoir County	4	21.0	17.7	24.2	29.8	24.0	35.7
56	37109	Lincoln County	4	14.3	12.2	16.3	20.1	16.5	23.7
57	37111	McDowell County	6	17.8	14.9	20.8	26.1	21.0	31.1
58	37113	Macon County	7	18.8	15.8	21.8	31.0	25.3	36.8
59	37115	Madison County	2	19.3	14.9	23.6	26.9	20.8	33.0
60	37117	Martin County	6	21.3	17.1	25.4	32.2	25.8	38.7
61	37119	Mecklenburg County	1	14.2	13.1	15.2	19.6	17.5	21.7
62	37121	Mitchell	9	18.3	14.6	22.0	26.5	20.8	32.1

		County							
63	37123	Montgomery County	6	21.3	17.2	25.3	31.2	24.9	37.6
64	37125	Moore County	4	13.3	11.0	15.6	21.9	17.9	25.9
65	37127	Nash County	3	15.6	12.8	18.3	22.7	18.1	27.4
66	37129	New Hanover County	2	16.0	14.2	17.7	21.2	17.9	24.6
67	37131	Northampton County	9	24.9	20.1	29.7	35.1	27.6	42.7
68	37133	Onslow County	3	15.1	12.4	17.9	21.0	17.1	24.8
69	37135	Orange County	2	16.9	15.2	18.6	14.7	12.3	17.0
70	37137	Pamlico County	9	18.6	14.6	22.5	30.3	23.7	36.8
71	37139	Pasquotank County	7	17.7	13.8	21.6	25.3	19.9	30.7
72	37141	Pender County	2	18.1	15.5	20.7	24.1	19.9	28.4
73	37143	Perquimans County	9	17.2	13.5	20.9	28.3	21.8	34.7
74	37145	Person County	2	14.6	11.3	17.8	20.7	16.1	25.4
75	37147	Pitt County	3	25.5	23.7	27.3	26.7	23.2	30.3
76	37149	Polk County	8	15.3	12.3	18.4	25.1	20.3	30.0
77	37151	Randolph County	2	16.0	14.0	18.1	23.6	19.8	27.4
78	37153	Richmond County	4	30.0	26.6	33.4	38.4	33.1	43.8
79	37155	Robeson County	4	31.1	27.6	34.6	43.8	38.2	49.3
80	37157	Rockingham County	2	14.9	12.3	17.4	22.3	17.7	26.9
81	37159	Rowan County	4	16.7	14.5	18.9	24.3	20.4	28.1
82	37161	Rutherford County	4	21.8	18.9	24.7	30.6	25.7	35.4
83	37163	Sampson County	6	21.7	18.5	24.8	28.4	23.0	33.9
84	37165	Scotland County	6	29.6	25.7	33.5	42.6	36.1	49.1
85	37167	Stanly County	6	14.1	11.4	16.7	21.2	16.8	25.6
86	37169	Stokes County	2	11.2	8.4	13.9	18.1	13.9	22.4
87	37171	Surry County	4	17.4	14.5	20.4	24.7	19.7	29.7
88	37173	Swain	8	17.6	13.9	21.3	26.6	20.7	32.6

		County							
89	37175	Transylvania County	6	19.9	17.3	22.6	35.2	30.0	40.4
90	37177	Tyrrell County	9	28.9	21.9	35.9	41.1	31.6	50.5
91	37179	Union County	1	10.9	9.5	12.3	14.5	12.3	16.7
92	37181	Vance County	4	32.3	28.8	35.8	48.0	42.3	53.8
93	37183	Wake County	2	10.2	9.4	11.0	12.1	10.4	13.9
94	37185	Warren County	8	26.1	21.3	31.0	37.0	29.7	44.2
95	37187	Washington County	7	23.3	18.3	28.4	37.1	29.1	45.1
96	37189	Watauga County	6	21.2	18.1	24.3	18.4	14.2	22.5
97	37191	Wayne County	3	20.0	17.8	22.3	29.0	25.4	32.6
98	37193	Wilkes County	6	18.5	16.0	21.1	30.0	25.4	34.5
99	37195	Wilson County	4	20.3	17.5	23.1	29.3	24.3	34.2
100	37197	Yadkin County	2	13.4	10.5	16.2	20.5	15.9	25.0
101	37199	Yancey County	8	17.8	13.5	22.0	28.8	22.2	35.3

See the county-level poverty rates from the 1990 and 2000 Census of Population.

Download the State- and county-level data in Excel format.

See important notes about intercensal model-based poverty estimates.

[1]The 2003 rural-urban continuum codes classify metropolitan counties (codes 1 through 3) by size of the Metropolitan Statistical Area (MSA), and nonmetropolitan counties (codes 4 through 9) by degree of urbanization and proximity to metro areas. See rural-urban continuum codes for precise definitions of each code.

Source: Bureau of the Census, Small Area Income and Poverty Estimates.

*See the Census Bureau web site for a description of FIPS codes.

For more information, contact: Kathleen Kassel

Web administration: webadmin@ers.usda.gov

Updated date: December 11, 2009

EXHIBIT

K

An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health

February 10, 2011

Prepared by

Gregory S. Vistnes, Ph.D.
Vice President
Charles River Associates
Washington, DC

An Economic Analysis of the Certificate of Public Advantage Agreement Between the State of North Carolina and Mission Health

I. EXECUTIVE SUMMARY

In late 1995, the only two acute-care hospitals in Asheville, North Carolina, merged to form Mission Hospital, an entity owned and operated by Mission Health Systems ("MHS").[1] Due to concerns that the merger would significantly increase Mission Hospital's market power in one or more markets in Western North Carolina ("WNC"),[2] the State of North Carolina entered into a Certificate of Public Advantage ("COPA") agreement with the hospitals as a condition for allowing the merger to go forward.[3] The regulatory requirements embodied in the COPA were designed to provide an offset to the competitive discipline being eliminated by the merger, thus helping to ensure that consumers would not face higher prices or reduced quality of care as a result of the merger.

In the years since the initial COPA agreement was entered into, health care markets have changed considerably. In recognition of this, the State of North Carolina commissioned this economic study to assess whether the existing Second Amended COPA (hereafter, simply "the COPA") should be modified in any way to better protect consumers against the loss of competition that resulted from the 1995 merger.[4] In assessing whether such modifications were warranted, I was asked to focus solely on competitive issues, and not to consider whether the COPA should be modified to better address policy issues such as access to care, the financial impact of the COPA on MHS or other entities, or the COPA's impact on physicians' incentives to practice in the WNC region.

The assessment of what, if any, modifications to the COPA are warranted is a very fact-specific one. In conducting this study, I collected and assessed information from a variety of sources, including interviews (both in-person and over the telephone) with individuals at MHS and other area hospitals, with health insurance plans operating in the WNC region, and with local physicians. I also reviewed and analyzed regulatory filings and data, public documents relating to competition in the WNC region, public data relating to physician admitting practices and

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[1] Memorial Mission Hospital and St. Joseph's Hospital signed a cooperative agreement in December 1995 to manage and operate the two hospitals as an integrated entity. Three years later, Memorial Mission Hospital acquired St. Joseph's Hospital under the ownership of Mission-St. Joseph's Health System, Inc. In December 2003, Mission-St. Joseph's Health System, Inc. was renamed Mission Health, Inc. and the merged hospitals were renamed Mission Hospital. In the remainder of this report I refer to the initial integration of the two hospitals, and their subsequent merger, simply as the 1995 merger. See the Second Amended Certificate of Public Advantage at pages 1 and 2.

[2] For the purposes of this report, I define the WNC region as the Service Area defined under the COPA (Section I Definitions): the 17 county region consisting of Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, and Yancey. For the purposes of this report, I define MHS's Primary Service Area ("PSA") as Buncombe and Madison counties.

[3] See the initial COPA agreement dated December 21, 1995. The COPA agreement was subsequently amended on October 8, 1998 to account for the formal merger of the two hospitals and again in June 2005 "to reflect changes in facts and circumstances, including the accomplishment or expiration of certain provisions of the COPA, and to provide better tools and mechanisms for oversight by the State." See Second Amended COPA at page 1.

[4] The two entities within the State that commissioned this study were the North Carolina Department of Health and Human Services and the Office of the Attorney General for North Carolina.

patient hospital choice, and confidential business data and documents. More generally, I drew upon my experience conducting similar types of economic analyses, especially in the area of hospital mergers, over the last 20 years as a private economic consultant at Charles River Associates and while serving in senior positions at the Antitrust Division of the U.S. Department of Justice and at the Federal Trade Commission's Bureau of Economics.

In assessing whether modifications to the COPA are warranted, I have adopted the following critical assumption: that the regulatory scope of the COPA should be limited to addressing competitive problems that arose as a result of the 1995 merger, and that the COPA should not seek to regulate conduct or markets that were unlikely to have been impacted by that merger. Rather, any problems that exist but that are unrelated to the 1995 merger should instead be addressed through other means such as existing state or federal antitrust laws, or existing Certificate of Need laws.

The motivating justification for the COPA's restrictions likely remains valid today: the 1995 merger likely resulted in a significant and enduring reduction in competition in one or more markets. Thus, the COPA's regulatory restrictions to replace that lost competitive discipline remain appropriate. Certain modifications of those regulations, however, are warranted as a means of increasing the regulatory protection that the COPA offers while simultaneously ensuring that the COPA is targeted solely on those areas where the merger likely reduced competition.

The four principal conclusions and recommendations from this study are summarized below.

1. ***The COPA's Margin Cap creates an incentive and opportunity for MHS to evade the intent of the COPA: by expanding into other markets (with respect to either geography or service), MHS can increase prices and realize higher margins than the COPA seeks to allow.***

   The COPA regulates MHS's average margin across all services and geographies. By expanding into lower-margin markets, MHS can reduce its average margin, thus allowing MHS to raise price without violating the Margin Cap. MHS can also lower its average margin, thus allow it to increase price, by incurring additional expenses that are not covered by the COPA's Cost Cap. Finally, although the Margin Cap is intended to protect commercial payers from incurring excessive rate increases, by looking at MHS's margin across both commercial and government payers, MHS may be able to impose excessive rate increases.

To address these problems, I recommend that:

- The existing Margin Cap should be replaced with a Price Cap so that MHS cannot meet its margin cap by incurring additional costs relating to services outside the scope of the Cost Cap.

- The Price Cap should only be applied to those markets originally affected by the merger, and a separate Price Cap should be calculated for each of those markets.

- The Price Cap should be limited to regulating prices to commercial payers, not to government payers or other payers for whom prices are unlikely to depend significantly on hospital competition.

2. ***The COPA's Cost Cap offers only limited regulatory protection for consumers, yet it creates undesirable incentives for MHS to increase outpatient prices and volumes.***

   The COPA's Cost Cap regulates Mission Hospital's inpatient and outpatient expenses, but does not prevent MHS from incurring excessive expenses relating to other markets or services (e.g., the cost of acquiring physician practices). As a result, it provides only limited protection to consumers. Moreover, if the COPA's Margin Cap is replaced by a Price Cap, then there may be little need for a Cost Cap. Finally, the methodology by which the COPA Cost Cap is calculated also creates an incentive for MHS to reduce the COPA's measure of expenses by increasing outpatient prices and, in some cases, by increasing outpatient volume.

   To address these issues, I recommend that:

   - The State should consider eliminating the COPA's Cost Cap. The greater the State's confidence in the effectiveness of a new Price Cap (to replace the existing Margin Cap), the greater the justification for eliminating that Cost Cap.

   - If the State retains the Cost Cap, then the COPA should address incentive problems relating to the Cost Cap methodology by adopting a separate Cost Cap for inpatient services and for outpatient services, and change the methodology by which "Equivalent Outpatient Discharges" are calculated.

3. ***The COPA creates an incentive and opportunity for MHS to engage in "Regulatory Evasion" by which MHS can evade price (or margin) regulation in one market by instead imposing price increases in a related, but unregulated, market.***

   MHS has an incentive to evade price (or margin) caps by tying the sale of its regulated services to other unregulated services, and then raising the price of that unregulated service. Although the COPA currently prevents MHS from tying with respect to physician services, I recommend that the scope of the COPA's restrictions on tying be expanded to also cover any other services that MHS offers.

   The State may also wish to also provide additional protection against Regulatory Evasion by requiring MHS to adopt contracting firewalls requiring MHS to contract separately, and with distinct contracting teams, for services in markets affected by the 1995 merger and for services in all other markets. In determining whether contracting firewalls are warranted, the State should balance what may be limited incremental benefits from these contracting firewalls with possible costs associated with impeding legitimate efforts by MHS to more fully integrate the provision of care between distinct contracting entities, and thus lower costs and improve quality.

4. ***The COPA's Physician Employment Cap may be unnecessary to address competitive concerns attributable to the 1995 merger.***

   The 1995 merger did not result in any significant reduction in competition between the two Asheville hospitals with respect to physician services, and thus the COPA's Physician Employment Cap is unnecessary to counter any merger-related increase in MHS's market power associated with physician services.

   An alternative merger-related justification for the COPA's physician restrictions is that the merger may have increased the risk that MHS could foreclose competition with rival hospitals by employing physicians that might otherwise split their practice between MHS and those rival hospitals. The evidence suggests, however, that the COPA's Physician Employment Cap may have limited value in preventing such a problem. On the other hand, the Physician Employment Cap may cause harm by preventing MHS from pursuing legitimate efforts to integrate care, and thus lower costs and improve quality. Thus, the State should consider dropping the COPA's restrictions on MHS's employment of physicians and instead let MHS's acquisitions of physician practices be governed by the same laws and regulations that govern other hospitals.

II. QUALIFICATIONS

I am an economist with a specialty in the fields of industrial organization and the economics of competition. I hold a Ph.D. in economics from Stanford University and a B.A. in economics from the University of California at Berkeley. I have published, made professional presentations, testified, and consulted in the areas of industrial organization, competition, and antitrust economics for approximately 20 years. A copy of my curriculum vitae is provided in Appendix 1.

During my professional career, I served as Deputy Director for Antitrust in the U.S. Federal Trade Commission's ("FTC's") Bureau of Economics. In that position, I was responsible for directing the economic analysis of all antitrust matters before the FTC and overseeing its staff of approximately 40 Ph.D. economists. Prior to that, I held several positions in the Economic Analysis Group of the U.S. Department of Justice's ("DOJ's") Antitrust Division, including Assistant Chief of the Economic Regulatory Section. In all of these positions, my antitrust analyses have focused on assessing competition and evaluating the likely competitive effects of firms' conduct.

I am currently a Vice President in the Washington, DC office of Charles River Associates ("CRA"), an economics and business consulting firm. At CRA, my work has focused almost exclusively on issues relating to competition, with a substantial portion of that work relating to both merger and non-merger matters before the FTC and the Antitrust Division of the DOJ, including matters in which I have been retained by the government to serve as an expert witness on its behalf.

Both while I was with the DOJ and FTC, and since joining CRA, I have been actively involved in analyzing competition in the healthcare industry. While at the DOJ, I was a member of the small working group that wrote, and subsequently updated, the DOJ/FTC *Statements of Antitrust Enforcement Policy in Health Care*. I also served during that period as a member of President Clinton's Health Care Task Force, and as a member of President Bush's Interagency Task Force on Information in the Health Care Industry. Since joining CRA, I have testified at the Federal Trade Commission/Department of Justice *Joint Hearings on Health Care and Competition Law and Policy*, and have been retained by private parties, and both state and federal antitrust agencies, to provide analysis and expert testimony regarding competitive issues in the health care sector. Finally, I have made presentations and published articles in peer-reviewed journals regarding competition in the health care industry.

III. BACKGROUND

The 1995 merger likely provided Mission Hospital with substantial market power with respect to inpatient services and possibly with respect to outpatient services.[5] The COPA addresses that market power through three principal regulatory constraints: a Cost Cap; a Price Cap; and a Physician Employment Cap.

A. Regulatory scope of the COPA

When analyzing competition, economists typically consider whether a firm enjoys significant market power, where market power can be thought of as a firm's ability to increase price above competitive levels. Here, the relevant question is whether the 1995 merger of Memorial Mission and St. Joseph in Asheville, the event which led to the original COPA agreement between the State and the hospitals, likely created significant market power in any relevant market. If so, then regulatory efforts to offset or reverse the effects of that increased market power may be appropriate.

However tempting it may be, the COPA should not be viewed as a vehicle for addressing competitive problems or healthcare policy issues that are unrelated to the merger. Rather, the regulatory scope of the COPA should be limited to addressing competitive problems that can be attributed to the 1995 merger.[6] Problems unrelated to the 1995 merger, to the extent they exist, should instead be addressed through existing state or federal antitrust laws and regulations (e.g., North Carolina's Certificate of Need laws).

B. The impact of the 1995 merger

The proper scope of the COPA depends on an assessment of where the merger likely created substantial market power. As discussed below, the 1995 merger likely only created significant market power regarding inpatient, and possibly outpatient, services.

1. Merger-related market power in inpatient hospital services

In assessing what, if any, modifications to the COPA are warranted, I have not been asked to address whether the 1995 merger resulted in substantially increased market power with respect to inpatient hospital services, and thus warranted regulatory restrictions: such an inquiry would go well beyond the scope of this study and require a much more fact-intensive inquiry. Instead, I

[5] References to inpatient and outpatient services in this report should be understood to refer to acute care and related medical services, not psychiatric, rehabilitation, substance abuse or other types of services.

[6] Regardless of any philosophical considerations about the proper scope for regulation, this limitation on the scope of the COPA is necessary purely from a practical perspective: unless the scope of the COPA is limited to merger-related issues, there is no clear boundary for how far-reaching the COPA's regulations should be. Absent those boundaries, there is no way in which to assess whether further modifications to the COPA are warranted so as to achieve those broader (but undefined) goals.

have assessed the COPA given the assumption of a merger-related increase in inpatient hospital services market power.

Yet, while I do not independently seek to assess whether Mission Hospital has market power relating to inpatient hospital services that stems from the 1995 merger, the evidence I have seen is fully consistent with that assumption. Prior to the merger, Memorial Mission and St. Joseph likely provided significant competition to each other. These two hospitals were located only blocks away from each other, and were both viewed as large, full-service hospitals. Consistent with what I have learned from health insurers operating in the area, those two hospitals appear to have provided important competitive discipline to each other. In contrast, other hospitals in the WNC region appear to have provided, and continue to provide, substantially less competitive discipline to the Asheville hospitals. Thus, by merging Memorial Mission and St. Joseph, the most important competitive discipline facing these hospitals appears to have been lost, thereby creating substantial market power.

The facts are generally consistent with this assumption that Mission Hospital realized significant market power from the merger. While potentially a very imperfect proxy for market power, Mission Hospital's share of inpatient discharges in several counties in WNC is consistent with the assumption that Mission Hospital enjoys substantial market power with respect to inpatient hospital services. As shown in Table 1, Mission Hospital's share of discharges from several counties in WNC is not only quite high (e.g., Mission Hospital accounts for approximately 90 percent of all hospitalizations of patients living in Buncombe County), it has been growing over time.

Mission Hospital is also significantly different in several regards from neighboring hospitals, thus likely reducing payers' willingness to substitute from Mission Hospital to those other hospitals. As shown in Table 2, Mission Hospital is substantially larger than other hospitals, both in terms of bed capacity and patient census. For example, Mission Hospital averaged approximately 522 patients/day in 2009, with the next largest hospital in WNC (Pardee Memorial Hospital in Henderson County) averaging only 72 patients/day. Mission Hospital is also substantially larger than other area hospitals in terms of the number of physicians actively admitting to the hospital: Mission has over 300 actively admitting physicians on its staff, while the next largest hospital in WNC has only 58.[7]

Mission Hospital also offers a broader, and more specialized, scope of services than do the other hospitals in WNC. For example, Mission Hospital is the only hospital in the WNC region offering Level II trauma care and is the recognized center for specialized care in the region. Consistent with this, other hospitals in the area generally recognize that Mission Hospital is an

[7] For the purposes of counting actively admitting physicians, I considered physicians with at least 12 admissions in the 12 month period ending June 30, 2010 (based on the State Inpatient data provided by Thompson Reuters). Alternative means of counting physicians (including counting only physicians that are not employed by a hospital) would not affect the conclusion that MHS has a much larger physician staff than any other local hospital.

important partner in providing healthcare services to the local community by offering services that those smaller hospitals cannot provide themselves. This difference in scope of services would make it difficult for payers to substitute away from Mission Hospital to those other hospitals in the region.

Geographic location also matters. In contrast to the two merging hospitals that now make up Mission Hospital and which were located only blocks away from each other, other hospitals in the WNC region are located many miles away from Asheville where managed care plans seek hospital coverage. The largest neighboring hospital (Pardee Memorial Hospital) that competes with Mission Hospital is approximately 25 miles away, while other hospitals in the WNC region are 15 to 110 miles away.

These data, as well as the information that I learned while interviewing physicians, health insurance providers and hospitals, are all consistent with the premise that Mission Hospital continues to enjoy substantial market power with respect to inpatient hospital services, and that this market power likely increased significantly as a result of the 1995 merger.

2. *Merger-related market power in outpatient hospital services*

I understand that both Memorial Mission and St. Joseph offered competing outpatient services at the time of the merger. Thus, the merger would have eliminated any competition between those two providers with respect to outpatient hospital services.

I have not sought to determine the extent to which Mission Hospital faces significant competition in the provision of those services. This competition could have come from physician clinics and offices, outpatient clinics or facilities, or other hospitals' outpatient facilities. Thus, I do not have a basis to conclude whether the merger likely created significant market power with respect to outpatient hospital services at the time of the merger or whether any such increased market power in outpatient hospital services remains today. Inasmuch as the COPA regulatory restrictions do cover outpatient services provided by Mission Hospital, however, I assume for the purposes of my study that the merger did create significant market power that endures today.[8]

3. *Merger-related market power and physician services*

I have seen no evidence suggesting that the creation of Mission Health resulted in a significant increase in market power with respect to physician services. In particular, I understand that neither of the merged hospitals employed any significant number of physicians prior to the

[8] If this assumption can be shown invalid, it may be appropriate to drop regulations in the COPA that relate to those outpatient services.

merger. Thus, the 1995 merger does not appear to have resulted in a significant increase in physician market power that warrants offsetting regulatory restrictions.[9]

C. The COPA imposes three principal regulatory constraints

I focus on three key regulations in the COPA: a Cost Cap; a Margin Cap; and a Physician Employment Cap.[10] A general description of those constraints is provided below.

1. The COPA's Cost Cap

Under the COPA, the rate at which Mission Hospital's "cost per adjusted patient discharge" ("CAPD") increases must not exceed the rate of increase in the producer price index for general medical and surgical hospitals in the U.S.[11]

The CAPD as defined by the COPA measures MHS's costs over both inpatient and outpatient operations, but only for the two merged Asheville hospitals. Thus, the scope of the COPA's Cost Cap regulation is appropriately limited to just those services and geographies for which the 1995 merger likely significantly increased MHS's market power.

2. The COPA's Margin Cap

Under the COPA, the operating margin of MHS over any three-year period shall not exceed by more than one percent the mean of the median operating margin of comparable hospitals (provided that this cap will not fall below three percent).[12]

The COPA's Margin Cap covers MHS's margins across its entire scope of operations: inpatient and outpatient, hospital and physician services, and all the geographic regions in which MHS operates. Thus, the scope of this regulation extends well beyond those services and geographies in which the 1995 merger likely significantly increased MHS's market power.

3. The COPA's Physician Employment Cap

Under the COPA, MHS is not permitted to employ, or enter into exclusive contracts with, more than 20 percent of the physicians practicing in Buncombe and Madison counties. This restriction

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[9] As discussed below, I have also considered whether the 1995 merger was likely to have increased concerns that MHS could engage in a vertical foreclosure strategy that might warrant regulatory restrictions relating to physician services.

[10] Although the COPA also includes other regulatory restrictions, I have seen no evidence suggesting that modifications to any of those restrictions is warranted.

[11] See Section 4.1 of the COPA.

[12] See Section 4.2 of the COPA.

applies to primary care physicians in each of the three following areas: family practice/internal medicine; general pediatrics; and obstetrics/gynecology.

D. The interplay between cost and margin caps

There exists an important interplay between the COPA's Cost and Margin caps in preventing problems that might otherwise emerge following the creation of significant market power following the 1995 merger. This interplay means that changes to one aspect of the COPA's regulatory structure cannot necessarily be done without regard to how, or whether, other aspects of the COPA's regulatory structure is changed.

The COPA's margin cap helps prevent post-merger price increases that might otherwise result from increased market power. Regulators often use margin caps, rather than price caps, in situations where the regulated firm's costs are likely to change over time in ways that the regulator cannot readily observe: since changes in costs normally warrant changes in a regulated price cap, the lack of cost observability can make a price cap difficult to implement. A margin cap, however, offers the promise of automatically compensating for changes in costs: higher costs allow the regulated firm to impose a comparable price increase while leaving margins unchanged.

A margin cap by itself, however, can be of limited effectiveness in regulating a monopolist. Absent additional regulation, a monopolist can meet its margin cap by simultaneously increasing both prices and costs. Moreover, while this strategy of spending any merger-related revenue increase may at first seem unattractive, in fact such a strategy may be quite attractive – especially for non-profit firms such as Mission Hospital.[13] For example, a non-profit hospital might have an incentive to increase post-merger prices to fund extensive architectural renovations that have little impact on quality of care, increased salaries that may (or may not) allow the hospitals to attract higher-quality employees, or investments in new medical technologies that yield significant consumer benefits (e.g., new operating rooms or new capital equipment). A regulated monopolist hospital may also respond to increased market power by raising prices so that it can fund an expanded scope of services (e.g., expanded outpatient services, offering a new transplant program, or acquiring physician practices) or to extend the geographic region in which it operates.

This incentive for a regulated monopolist to increase costs as a way of relaxing a margin cap can be addressed by imposing a cost cap along with the margin cap. Note, however, that in order to be fully effective, the cost cap needs to be broad enough in scope that it covers all areas that are covered by the margin cap. For example, if the margin cap covers all geographies and services

[13]While I use the economic terminology "monopolist" throughout this report to describe certain economic phenomenon that are relevant to understanding MHS's incentives and the COPA, and while I believe that MHS likely enjoys substantial market power in certain markets, I do *not* mean to suggest that MHS is a monopolist facing absolutely no competition.

(as is the case with the COPA Margin Cap), then a cost cap that is limited to costs relating to inpatient and outpatient services in a particular geography (as is the case with the COPA Cost Cap) will still allow the monopolist to increase inpatient and outpatient prices, yet still meet the margin cap by increasing expenditures relating to physician services or by opening or acquiring facilities in other geographies outside the scope of the Cost Cap.

IV. INCENTIVE PROBLEMS UNDER THE EXISTING COPA REGULATIONS

Economists have long recognized the difficulties of regulating monopolists and how regulation, no matter how carefully crafted and implemented, can inadvertently create undesirable incentive problems. Not surprisingly, some of these incentive problems emerge with respect to the COPA's regulation of MHS.[14] These problems are described below, with recommendations on how the COPA can be modified to address those problems provided in the next section.

A. Incentive problems created by the Cost Cap

The COPA's Cost Cap suffers from two problems. First, the mechanics of how Mission Hospital's costs are calculated creates an incentive (whether or not it is acted upon) for MHS to game the system: by increasing outpatient prices, MHS makes it easier to meet its Cost Cap. Second, the scope of the Cost Cap is too narrow to adequately prevent MHS from raising prices with respect to inpatient or outpatient services at Mission Hospital, and then using those merger-related revenues to expand into other services or geographies.

1. Incentives to raise outpatient prices and expand outpatient services

The COPA's Cost Cap limits Mission Hospital's "cost per adjusted patient discharge" ("CAPD"). The manner in which the COPA defines the CAPD, however, has the effect that Mission Hospital can increase its number of effective calculated outpatient discharges, thus lower the CAPD, by increasing outpatient prices. This can be seen by looking at the specifics by which the CAPD is calculated.[15]

1) Calculate Mission Hospital's "case mix adjusted discharges" by multiplying its inpatient discharges by its case mix index.

2) Calculate Mission Hospital's "revenue per inpatient discharge" by dividing its inpatient revenue by its case mix adjusted discharges (as calculated in (1) above).

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[14] It should be stressed that although some of MHS's conduct appears to be consistent with the incentive problems I identify below, I offer no opinion as to whether MHS has actually acted on those incentives. Addressing that question would likely require an extremely fact-intensive investigation.

[15] See Section 4.1 of the COPA.

3) Calculate Mission Hospital's "equivalent outpatient discharges" by dividing its outpatient revenue by its revenue per inpatient discharge (as calculated in (2) above).

4) Calculate Mission Hospital's "total adjusted discharges" by adding its case mix adjusted discharges and its equivalent outpatient discharges (as calculated in (3) above).

5) Calculate Mission Hospital's "cost per adjusted patient discharge " (CAPD) by dividing its operating expenses by total adjusted discharges (as calculated in (4) above).

In essence, the COPA calculates the CAPD by first defining a common measure of volume across both inpatient and outpatient services. The COPA does this by defining a unit of outpatient service (the "equivalent outpatient discharges") as the volume of outpatient services that ends up equalizing inpatient revenue per unit and outpatient revenue per unit. This is illustrated in the Base Case in Table 3 which provides a hypothetical example in which the hospital is assumed to do 1,200 inpatient procedures at a price of $1,000/procedure, and 800 outpatient procedures at a price of $800/procedure. Here, the "equivalent outpatient discharges" is calculated so that the price per procedure is equalized at $1,000 for both inpatient and outpatient procedures. Once outpatient volume is calculated in this way, Table 3 shows how it is straightforward to then calculate the hospital's "cost per adjusted patient discharge" (based on the hospital's assumed costs).

Calculating Mission Hospital's CAPD in this way, however, creates a serious incentive problem. As illustrated in the middle block of Table 3, Mission Hospital can increase outpatient revenue by increasing outpatient prices. That increased outpatient revenue in turn increases the number of "equivalent outpatient discharges" that are calculated according to the COPA methodology.[16] That increased number of equivalent outpatient discharges will, in turn, increase total adjusted discharges, and thus reduce the calculated CAPD: as illustrated in Table 3, the assumed 20 percent outpatient price increase lowers the CAPD from $800 to $762, a reduction of almost 5 percent. Thus, the COPA creates an incentive for Mission Hospital to lower its CAPD, and make it easier to meet the Cost Cap, by raising outpatient prices.[17]

The COPA Cost Cap may also create an incentive for Mission Hospital to increase outpatient volume as a means of lowering the calculated CAPD. Just like an increase in outpatient prices, increased outpatient volumes increase equivalent outpatient discharges. Increased outpatient volume, however, will also increase Mission Hospital's operating expenses. Whether that increase in outpatient volume increases, or reduces, the CAPD will depend how much the increase in outpatient volume increases total expenses. This effect is illustrated in the bottom

[16] In essence, the COPA defines a unit of outpatient services to be equal to $1,000 worth of outpatient services. If the prices for all individual outpatient services increase, then the actual volume of outpatient services associated with that $1,000 of outpatient care has to fall. Thus, even with no change in the actual amount of outpatient care, the measured volume of outpatient care (i.e., a package of $1,000 of outpatient care) will increase.

[17] As discussed in more detail below, the COPA's Margin Cap cannot be relied upon to prevent this increase in outpatient prices.

block of Table 3 which shows how increasing outpatient volume by 20 percent in addition to increasing outpatient prices by 20 percent can further reduce the CAPD.[18]

2. *Differing scope of the Cost Cap and the Margin Cap*

The principal purpose of the Cost Cap is to prevent MHS from meeting its Margin Cap by pairing price increases with an accompanying increase in costs, and thus keeping margins unchanged. Yet, the Cost Cap can only prevent this form of regulatory evasion if the scope of the Cost Cap is as broad as the scope of the Margin Cap.

The COPA's Cost Cap, however, only covers inpatient and outpatient services provided by MHS's Mission Hospital. Thus, while the Cost Cap prevents MHS from spending money relating to post-merger price increases on inpatient and outpatient services in Asheville, the Cost Cap does not prevent MHS from satisfying the Margin Cap by spending merger-related revenues in other areas, e.g., expanding its geographic reach outside Mission Hospital's PSA, or expanding the scope of services it provides in Mission Hospital's PSA.

B. Incentive problems created by the Margin Cap

The COPA's Margin Cap creates several undesirable incentives that should be addressed.

1. *The COPA creates incentives for MHS to increases its costs*

As discussed, MHS has an incentive to evade the Margin Cap by pairing price increases in markets where it enjoys market power with accompanying cost increases. Moreover, the COPA's Cost Cap cannot be relied upon to prevent these cost increases since the Cost Cap does not cover all services or geographies.

2. *The COPA may create an unfair competitive advantage for MHS*

The COPA's Margin Cap creates an incentive for MHS to engage in cross-subsidization across markets whereby it raises price in those markets where it has market power, and uses those revenues to subsidize its operations in other more competitive markets. Thus, the Margin Cap creates an incentive for MHS to offer particularly low prices when expanding into new geographic regions (e.g., offering outpatient services in counties other than its PSA) or offering new services. This willingness to offer particularly low prices, while benefitting consumers in the short run, could lead to market distortions and create what might be viewed as an unfair advantage for MHS relative to other competitors.

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[18] Mission Hospital has, in fact, been increasing its outpatient revenues more rapidly over time than its inpatient revenues. From 2004 to 2009, Mission Hospital's inpatient gross revenues increased by approximately 57 percent, while its outpatient gross revenues increased by approximately 77 percent. As a result, outpatient services increased from approximately 30 percent of Mission Hospital's gross revenue to 33 percent.

The Margin Cap also creates an incentive for MHS to lower its margin by paying higher-than-normal prices for certain inputs. This might take the form of MHS being willing to pay more than others in competitive bidding for hospitals, for empty land on which to build new facilities, or to outbid rivals when purchasing physician practices.

3. The COPA creates incentives for MHS to expand into low margin markets

The COPA's Margin Cap requires that MHS's average margin across all services and all geographies not exceed a specified margin. MHS, however, can reduce its average margin, and thus make it easier to meet the Margin Cap, by expanding into new services and geographies in which MHS anticipates realizing a lower-than-average margin.[19]

The incentive for MHS to expand operations to lower-margin markets is consistent with the observation that, by adding McDowell Hospital and Blue Ridge Hospital to its system, MHS has reduced its average margin subject to the COPA's Margin CAP: as shown in Table 4, by expanding its scope of operations beyond just Mission Hospital, MHS's operating margin falls from approximately 5.1 percent to 4.5 percent.[20] Similarly, the margins at two other hospitals with which MHS is in the process of affiliating (Transylvania Community Hospital and Angel Medical Center) are also likely to be lower than the margin at Mission Hospital.[21] Thus, if either of those two hospitals were eventually acquired by MHS it would likely further reduce the average margin that is currently subject to the Margin Cap.

4. The Margin Cap may provide limited relief for commercial payers

Because Medicare and Medicaid payments to hospitals are largely unaffected by competition, the principal category of payers requiring protection from the reduced competition resulting from the 1995 merger are commercial health plans and their enrollees. The COPA Margin Cap, however, does not distinguish between MHS's margin on commercial accounts versus its margin relating to other patients (e.g., Medicare, Medicaid and self-pay/uninsured). To the extent that Medicare and Medicaid patients represent lower margin business (as generally believed to be the case), then MHS's margin on commercial patients can exceed the Margin Cap, even though MHS's average margin will still meet that Margin Cap.

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[19] The COPA's Cost Cap cannot be relied upon to prevent this type of expansion into low-margin services and geographies: as noted above, the COPA's Cost Cap only covers Mission Hospital's inpatient and outpatient services, and would not prevent MHS from expanding into other services (e.g., employing more physicians) or into other geographies.

[20] I do not address whether MHS's expansion into these low-margin markets serves some other important public policy goal, e.g. the infusion of necessary capital or helping to ensure that a hospital can remain open.

[21] Although I do not have data confirming these relative margins, small rural hospitals such as Transylvania Community Hospital and Angel Medical Center frequently face significant financial difficulties, with those financial difficulties oftentimes a reason for why those hospitals seek a relationship with a financially stronger partner.

The greater MHS's share of Medicare and Medicaid patients (or more generally, the greater the share of non-commercial pay patients with low margins), the more that MHS's margin on commercial patients can exceed the regulated Margin Cap. With the COPA's regulated margin cap based on margins at comparable hospitals,[22] then if MHS's payer mix becomes more heavily weighted towards Medicare and Medicaid than those comparable hospitals, MHS will be able to increase prices to commercial payers without exceeding the regulated Margin Cap.[23]

C. The COPA creates incentives for Regulatory Evasion

The COPA creates an incentive for MHS to engage in what economists often refer to as "Regulatory Evasion," a situation in which a regulated monopolist responds to price regulation in one market by instead raising prices in a second unregulated market.[24] In the context of the COPA, this evasion can arise if MHS, unable to increase inpatient or outpatient prices because of regulation, instead increases the price it charges for unregulated services such as physician services or services at another facility. If MHS can condition the sale of its regulated inpatient or outpatient services (where it likely has significant market power) on a health insurers' willingness to also purchase its higher-priced unregulated service, then MHS essentially "shifts" the market in which it extracts its higher price.[25]

The traditional approach to preventing Regulatory Evasion is to attempt to prevent the monopolist from tying its regulated product to some other unregulated problem. If those ties can be prevented, then the monopolist can no longer impose a price increase in the secondary market since consumers no longer need to purchase that higher-priced product as a condition to purchasing the regulated product.

The COPA currently incorporates language that limits MHS's ability to engage in a tie by requiring that MHS "shall not require managed-care plans to contract with its employed doctors

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[22] See Section 4.2 of the COPA.

[23] According to data provided by MHS, Medicare and Medicaid accounted for approximately 63 percent of its gross revenue in 2008 (increasing slightly to 65 percent in 2010). This is slightly higher than the nationwide average across community hospitals in which Medicare and Medicaid accounted for approximately 56 percent of gross revenue in 2007. (See "The Economic Downturn and Its Impact on Hospitals," The American Hospital Association, January 2009, page 4). It is also higher than the average for hospitals rated by Moody's Investors Service as Aa2 and Aa3 in which Medicare and Medicaid accounted for approximately 48 percent and 50 percent of gross revenue, respectively. These Moody's credit rated hospitals are particularly relevant because the operating margins at these hospitals are used in part to determine the operating margin benchmark specified by Section 4.2 of the COPA. (See "Moody's U.S. Public Finance – Not-for-Profit Hospital Medians for Fiscal Year 2008," Moody's Investors Service, August 2009, page 21).

[24] Regulatory evasion can also occur when the second market is regulated, as long as the second market is somehow "less" regulated.

[25] It may seem that the solution to Regulatory Evasion is to expand the scope of regulation by extending price (or margin) caps to those secondary markets. Expanding the scope of regulation, however, can create a slippery slope of increased regulatory entanglement in which price (or margin) caps end up being applied to an increasing number of otherwise competitive secondary markets in an effort to prevent the monopolist from finding a market in which it can shift its price increase.

as a precondition to contracting with it or its constituent hospitals."[26] This language, however, only succeeds in preventing MHS from tying physician services to its sale of hospital services, while failing to prevent possible ties between Mission Hospital and other MHS services such as outpatient services in other geographies, or inpatient services provided at other MHS hospitals.

D. MHS conduct appears to be consistent with incentive problems

The incentive problems associated with the COPA regulation appear to be consistent with MHS's observed conduct and complaints about MHS's conduct that have been voiced by certain parties.[27]

1. MHS expansion into other geographies and services

The COPA creates a variety of incentives for MHS to expand its operations into other services and into new geographies. These incentives are consistent with MHS's historical conduct, as well as its possible plans for the future:

- MHS historically expanded its hospital network with the acquisition of Blue Ridge Regional Hospital in Mitchell county and the McDowell Hospital in McDowell county;
- MHS further expanded its hospital network by recently agreeing to manage the operations of Transylvania Community Hospital in Transylvania county;[28]
- MHS has plans to further expand its hospital network to include Angel Medical Center in Macon county;[29]
- MHS attempted to expand its scope of hospital operations by bidding to manage the operations of Haywood Regional Medical Center in Haywood county and the WestCare Health System with hospitals in Swain and Jackson counties;[30]

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[26] See Section 5.2 of the COPA.

[27] It is worth repeating that, while the above-mentioned conduct is consistent with the previously discussed incentive problems created by the COPA, I have not sought to determine the extent to which the COPA likely caused any of that conduct. Yet, even without showing that MHS is necessarily acting on these incentives to any significant degree, it would be prudent to seek to reduce or eliminate those incentive problems.

[28] MHS recently announced that it will manage Transylvania Community Hospital and its affiliates as of January 1, 2010. See Mission Health System press release dated December 27, 2010.

[29] According to a recent publication, "[o]n May 13, Angel Medical Center's Board of Trustees decided to actively begin exploring a potential partnership with the Asheville-based Mission Health System." See "Angel Medical Center and Mission Health System consider partnership," The Macon County News, May 27, 2010.

[30] Press release: "HRMC, WestCare move forward together with Carolinas HealthCare System," Haywood Regional Medical Center (http://www.haymed.org/about/news-and-events/43-main-news/63-hrmc-westcare-move-forward-together-with-carolinas-healthcare-system.html).

- Concerns have been expressed that MHS plans to further expand its scope of employed physicians;

- MHS has plans to engage in a joint venture with Pardee Hospital to construct a new outpatient facility on the Buncombe/Henderson county line;[31]

2. *MHS expansion into lower margin services*

Consistent with MHS's incentive to expand into lower margin services as a means of lowering its average margin and thus relaxing the margin constraint, MHS continues to expand its relationships with rural hospitals that enjoy lower margins than the rest of MHS's operations.[32] This comparison of margins is shown in Table 4.

3. *Joint contracting across services and geographies*

Regulatory Evasion could be achieved by MHS tying the sale of Mission Hospital's inpatient and outpatient services to the sale of some other more competitively provided service. This is consistent with what I understand MHS's contracting practice to be. In particularly, I understand that, while MHS typically enters into separate contracts at separate rates for its different services (e.g., it does not charge the same rates for Mission Hospital as it does for its Blue Ridge hospital), there is at least some degree of informal linkage between these contracts. I also understand that the contracting personnel at MHS and at the managed care plans are generally the same individuals, and the contracts for MHS's different hospitals and services are generally negotiated concurrently.

4. *Concerns about "unfair competition"*

In the course of my interviews, some providers have expressed concerns that, as MHS has expanded the geographic scope of the services it offers, those providers will be at a competitive disadvantage. To some extent, this concern may simply reflect a competitor's normal concern that, as a new rival comes to town, there will be some loss of business.[33]

Concerns about MHS's entry into new geographic or service markets, however, are also consistent with the fear that MHS is competing on an unequal competitive footing. In particular, concerns about competing with MHS may stem from MHS's potential incentive to cross-

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[31] Press release: "Mission and Pardee Announce Collaboration to Expand Healthcare Services," Mission News, July 1, 2010 (http://www.missionhospitals.org/ body.cfm?id=111&action=detail&ref=141).

[32] Policymakers will have to decide whether they view this incentive effect of the COPA as a good, or a bad, thing. While MHS's incentive to acquire those hospitals may reflect a market distortion caused by the COPA, policymakers may ultimately conclude that the benefits of the financial support that MHS provides those hospitals outweighs any harm from that market distortion.

[33] This concern would be heightened if the entrant came to town with a reputation for high quality service and the ability to offer certain services that the incumbent was less capable of offering.

subsidize services and offer lower-than-normal prices on new services so as to avoid exceeding the Margin Cap, or to offer higher-than-normal prices when competing to acquire physician practices or existing healthcare facilities.

V. ADDRESSING THE INCENTIVE PROBLEMS CREATED BY THE COPA

To address the previously discussed incentive problems, I recommend several modifications to the COPA.

A. Changing the Margin Cap to a market-specific Price Cap

I recommend that the COPA replace its existing Margin Cap with a Price Cap that limits the annual amount by which an aggregated measure of price can increase. Perhaps the most important reason for recommending this change is that the usual reasons for relying on a margin cap rather than a price cap do not apply here. As previously discussed, economists typically rely on margin caps when a price cap is not workable. This is most often the case when there are likely to be significant unobservable cost changes over time that would otherwise necessitate changes in the price cap. Absent a means to either observe underlying cost changes, or to observe how prices should be changing by looking at other (competitive) markets, a price cap may be impractical. Those impediments to a price cap, however, do not exist here. In particular, price changes over time can be regulated to ensure they do not exceed price increases at comparable hospitals in competitive markets.

Switching from a margin cap to a price cap should improve regulation in several ways. First, a price growth cap is a more direct means of addressing the concern that the 1995 merger created market power that allows MHS to raise price. Second, a price cap eliminates MHS's ability to evade the margin cap by inflating expenses along with prices. Third, a price cap eliminates the incentives that a margin cap can create for cross-subsidization, creating unfair competition, and creating distorting incentives by promoting MHS entry into low-margin markets. Fourth, switching from the Margin Cap to a price cap will make it easier for regulators to focus the regulation on those markets originally affected by the 1995 merger: inpatient and outpatient services at Mission Hospital.[34]

In designing a new Price Cap for the COPA, the following considerations should apply:

- The Price Cap should regulate rates of change over time, not absolute levels.[35]
- There should be separate Price Caps that apply to inpatient and to outpatient services.

[34] This focus would be much more difficult to achieve with a Margin Cap given the difficulties that would arise in allocating costs that were common across a variety of services or different geographies.

[35] This approach, unfortunately, locks in any excessive rates that Mission Hospital may already be charging.

- The Price Cap should apply only to those markets originally affected by the merger: inpatient and outpatient services in Mission Hospital's PSA.

- The Price Cap should only apply to, and be calculated with respect to, commercial payers.[36] This focus on commercial payers is consistent with the view that the original merger only affected competition for commercial contracts, and thus the regulation should only be directed at controlling price increases to that payer segment.

Calculating Mission Hospital's price for use in a price cap will involve three steps. First, a measure of Mission Hospital's case-weighted output should be defined, separately for inpatient and for outpatient services.[37] Second, Mission Hospital's net patient revenue should be determined, separately for inpatient and for outpatient services. Third, net patient revenue should be divided by case-weighted output to obtain an average case-mix adjusted price across all inpatient services, and across all outpatient services. Increases in these case-mix adjusted prices can then be restricted to not exceed increases of a suitably defined index.[38]

Should the State replace the Margin Cap with a Price Cap, the State needs to decide whether that Price Cap should encompass the services that MHS hopes to offer at its proposed joint venture facility to be located on the Buncombe/Henderson county line.[39] As discussed below, a decision not to extend the Price Cap to cover those joint venture services may create strong incentives for MHS to engage in regulatory evasion whereby it seeks to force payers to purchase services from the joint venture but pay prices that exceed competitive levels. Thus, the State's decision not to extend the Price Cap to those services should depend on its comfort that it can prevent such Regulatory Evasion. Ultimately, however, I believe that the State can sufficiently limit concerns regarding Regulatory Evasion so that it is *not* necessary to extend the Price Cap to cover the joint venture's services.

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[36] I recommend that the Price Cap apply to MHS's net revenues across all commercial payers rather than having the cap apply to each individual payer. A payer-specific Price Cap may be impractical and undesirable for several reasons. First, a payer-specific cap would leave open the question of how much MHS could charge a new payer. If no restrictions applied, the MHS would have strong incentives to charge a very high initial price so that subsequent growth would leave the Price Cap at a very high level. Such incentives would also reduce the likelihood that new payers would seek to enter the Asheville area, an undesirable outcome given the apparently very high payer concentration in the Asheville region. Second, a payer-specific cap would be more difficult to practically implement given that hospital rates to payers typically depend significantly on payer volume.

[37] For inpatient services, this can be done in the same way that case-mix adjusted discharges are calculated for purposes of the COPA's Cost Cap (see Section 4.1 of the COPA). For outpatient services, a comparable approach can be used; such approaches are used, for example, by the Centers for Medicare and Medicaid Services for use in the Outpatient Prospective Payment System.

[38] The COPA already uses a Producer Price Index for general medical and surgical hospitals, as well as an index of comparable hospitals (see Section 4.1 of the COPA) in calculating acceptable cost changes.

[39] See note 31.

B. Dropping, or revising, the Cost Cap

The principal motivation for the COPA's Cost Cap is to prevent MHS from increasing expenditures as a means of satisfying the Margin Cap. Once the Margin Cap is replaced by a Price Cap, however, the Cost Cap is largely relegated to providing "backup regulation" in the event that the Price Cap is imperfect. Accordingly, as long as the State replaces the COPA's Margin Cap with a Price Cap, the State should consider dropping the COPA's Cost Cap entirely.

Should the State choose to retain the Cost Cap as a type of regulatory backup to the Price Cap, that Cost Cap should be revised to eliminate the incentive that it currently gives Mission Hospital to increase outpatient prices, and possibly expand outpatient volume, as a means of reducing the estimated cost per adjusted patient discharge. As previously noted, this problem stems from how the COPA calculates equivalent outpatient discharges, and it can be addressed by adopting the following two changes.

- ***Adopt a separate Cost Cap for inpatient services and for outpatient services.*** Separating the Cost Cap for inpatient and outpatient services means that it is no longer necessary to find a common output measure for both inpatient and outpatient procedures.[40] As previously discussed, this need to find a common measure of output created the incentive for MHS to increase outpatient prices and possibly outpatient volumes.

- ***Calculate Case-Weighted Outpatient Discharges.*** Case-weighted outpatient discharges should be calculated in the same way that outpatient volume is calculated when estimating an average outpatient price for use in a new Price Cap.[41]

C. Reducing Regulatory Evasion concerns

Replacing the Margin Cap with a Price Cap, and then limiting that Price Cap to just Mission Hospital's inpatient and outpatient services, increases incentives for MHS to engage in Regulatory Evasion in which it would instead raise prices in unregulated secondary markets such as physician services. As mentioned above, this concern may be particularly acute with respect to MHS's proposed joint venture with Pardee Memorial Hospital.

The cleanest means of preventing Regulatory Evasion is to prevent tying, explicit or otherwise. Accordingly, the COPA's existing language prohibiting tying of physician services should be extended to prevent MHS from requiring managed care plans to contract with any of its

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[40] This may, however, create certain problems relating to allocation of costs that are common to both inpatient and outpatient services, e.g., certain corporate costs, certain facilities costs, and certain capital costs associated with technology that is used for both inpatient and outpatient procedures.

[41] See note 37 above.

employed physicians *or any other MHS service provider* as a precondition to contracting with Mission Hospital.[42]

Imposing a regulatory prohibition on tying, however, may be insufficient to completely solve the Regulatory Evasion problem: firms often have a variety of ways of imposing ties that are not clearly in violation of regulatory language.[43] Accordingly, the State should be vigilant in guarding against such tying, whether explicit or implicit, and particularly with respect to the proposed joint venture with Pardee Memorial Hospital where incentives to engage in Regulatory Evasion might be particularly strong.

Should the State become concerned that that a "no tying" restriction will be insufficient to protect against Regulatory Evasion, the State may wish to add language in the COPA that gives the State the option of making such tying more difficult by requiring a contracting firewall between MHS's inpatient and outpatient services at Mission Hospital and the other services it provides. This contracting firewall could include the following elements:

- That the COPA require MHS to establish distinct contracting teams: one of which focuses on MHS's contracts relating to Mission Hospital in Asheville and its operations, the other of which focuses on all other services and geographies (including all physician-related contracts and contracts with McDowell Hospital and Blue Ridge Regional Hospital);

- That the two MHS contracting teams maintain an information firewall to prevent communications or coordination across contracting;

- That MHS does not engage in simultaneous contracting for Mission Hospital and any other MHS service provider (e.g., McDowell Hospital).

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[42] The joint venture may also create strong incentives to engage in another form of Regulatory Evasion: substitution of where MHS offers its services: if services offered at Mission Hospital are covered by the price cap, but similar services offered at the joint venture are not covered by the price cap, then MHS has incentives to shift patients from the regulated Mission Hospital to the unregulated joint venture (presuming that MHS can tie the sale of those joint venture services in a way that allows it to realize higher-than-competitive prices at the joint venture). In fact, I understand that an express goal of MHS is to shift the location where it treats many of its patients from Mission Hospital to the new joint venture facility. I note, however, that Mission Hospital argues that such shifting is an important means of improving healthcare quality and access to care given its concern that Mission Hospital has little slack capacity. Thus, by shifting patients, MHS has indicated that it hopes to better serve the community by focusing on more complex care at Mission Hospital while shifting less complex care to other sites that may be closer to where patients actually live. If, however, tying between Mission Hospital and the joint venture can be prevented, then MHS can pursue its goal of shifting patients, and thus benefitting consumers, without raising any concomitant concerns about Regulatory Evasion.

[43] The alternative regulatory approach of trying to prevent regulatory evasion by extending price (or margin) regulation into otherwise unregulated secondary markets, however, seems even less attractive and less beneficial to consumers.

The value of a contracting firewall, however, is unclear. In particular, a contracting firewall is a cumbersome regulatory obligation that may create inefficiencies for both payers and MHS.[44] Moreover, even contracting firewalls often fail to operate as cleanly and as effectively as might be wished. As a result, I recommend that, even if the State opts to include language in the COPA regarding contracting firewalls, those firewalls only be imposed if the State concludes that tying is occurring in a way that cannot otherwise be prevented through the "no tying" language of the COPA.

VI. THE COPA'S RESTRICTIONS ON PHYSICIAN EMPLOYMENT

The COPA's restrictions on physician employment do not appear necessary to address concerns that the 1995 merger reduced competition relating to physician services. Those restrictions also appear to be of limited value in preventing a merger-related problem associated with MHS foreclosing competition with rival hospitals by restricting those rival hospitals' access to physicians. As a result, I recommend that the State consider dropping the COPA's Physician Employment Cap, and instead let MHS's acquisitions of physician practices be governed by the same laws and regulations that govern other hospitals.

A. The 1995 merger did not significantly reduce physician competition

At the time of the 1995 merger, neither of the merging Asheville hospitals employed a significant number of physicians. As a result, the merger did not significantly increase Mission Hospital's market power with respect to physician services. It follows that COPA regulation of physician services is not necessary to counter any merger-related creation of market power.[45]

B. The 1995 merger and foreclosure concerns

Physician employment by MHS creates a potential foreclosure concern involving MHS employing physicians as a means of harming rival hospitals. To the extent such foreclosure is deemed possible, and that the 1995 merger increased the either likelihood of, or effects from, such foreclosure, the COPA's Physician Employment Cap may be warranted. As discussed below, however, I have seen little evidence that such foreclosure concerns are sufficiently likely to warrant restrictions on how many physicians MHS can employ.

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[44] My discussions with payers, however, indicate that, despite the inefficiencies that firewalls and sequential contracting will likely create, they tend to either support, or be neutral towards, requiring such a firewall.

[45] I have also considered whether the merger might have resulted in buy-side market power (typically referred to by economists as "monopsony power"). Yet, even if the merger had created buy-side market power (a supposition for which I have seen no evidence), a cap on physician employment would not be the proper regulatory solution.

1. *Foreclosure concerns and rationale for a Physician Employment Cap*

In the course of my interviews with different health care providers in WNC, several MHS rivals have expressed a variant of the following type of foreclosure concern. By employing physicians, MHS may be able to cause those physicians to shift their admissions from rival hospitals to MHS (their new employer). By employing enough physicians, MHS might reduce admissions at rival hospitals by so much that those rival hospitals become financially, and thus compressively, weakened.[46] In addition, by employing enough physicians who previously admitted at rival hospitals, MHS might increase the importance of MHS, and reduce the importance of those rival hospitals, to managed care plans. This, in turn, would make it more difficult for those managed care plans to drop MHS hospitals from their network, and thus result in reduced competition. Thus, a cap on the number of physicians that MHS can employ might be necessary to prevent such foreclosure.

The foregoing foreclosure concern is also generally consistent with the COPA's existing Nondiscrimination restrictions.[47] Those restrictions prevent MHS from requiring physicians to render services only at MHS hospitals, consistent with an underlying foreclosure concern. The COPA's nondiscrimination restrictions do not, however, apply to MHS's employed physicians. Thus, the COPA's Physician Employment Cap can be viewed as a complement to the Nondiscrimination restriction by helping to ensure that MHS does not control too many physicians' admitting decisions, and thus cannot put rival hospitals at too much at risk of having MHS cut off their access to the physicians that they rely upon for patients.

2. *The likelihood of successful foreclosure by MHS*

In order for the foreclosure concern to be appropriately addressed by the COPA (rather than other antitrust or competition laws that address foreclosure concerns), the foreclosure concern should be related to the 1995 merger. The evidence, however, provides little support for the belief that the 1995 merger increased the likelihood that such a foreclosure by MHS would be successful.

The most likely means by which the 1995 merger might have increased foreclosure concerns is that the merger may have given MHS the ability to "force" physicians into employment contracts that they otherwise would rejected.[48] The evidence, however, suggests that MHS is not in a position where it can force such employment contracts on physicians.

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[46] Whether or not this shift in admitting patterns would occur in reality is unclear. I understand that MHS claims that, for physicians located outside of Buncombe County, it does not necessarily seek to change that physician's admitting patterns. At this point, the empirical evidence relating to such practice acquisitions is too sparse to properly evaluate this issue.

[47] See Section 6.1 of the COPA.

[48] Perhaps the only other possible linkage between the 1995 merger and the foreclosure concern is that the 1995 merger likely increased the harm that would likely result from foreclosure (if, in fact, MHS successfully engaged in

- MHS's employment of a physician will have the greatest impact on a rival hospital when that physician admits a significant number of patients to the rival hospital.[49] Yet physicians that already rely heavily on a rival hospital would be the least vulnerable to pressure from MHS. Conversely, those physicians that are most vulnerable to MHS pressure would be the ones that admit most of their patients to Mission Hospital, meaning that rival hospitals would lose little if those physicians began admitting exclusively to Mission Hospital.[50]

- There have been instances in which MHS has sought to employ a physician, yet that physician has turned down MHS's offer and instead remained unaffiliated or else affiliated with a different organization.

- One of the factors behind the recent departure of MHS's CEO is that local physicians were unhappy with what they perceived to be excessive pressure from MHS regarding the nature of their affiliation with MHS.[51] Thus, MHS's ability to force employment contracts on local physicians appears quite limited.

C. Restrictions on physician employment may harm consumers

In assessing whether to eliminate the COPA's restrictions on physician employment, the State should consider what, if any, consumer harm may result from those restrictions. Such harm should be balanced against what the previous discussion suggests are limited benefits from those restrictions.

The Physician Employment Cap may cause harm in several ways. First, unnecessarily regulating MHS with respect to physician services may effectively handicap MHS in its ability to compete

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a foreclosure strategy). The 1995 merger increases the harm from foreclosure since, by significantly reducing competition for inpatient hospital services, further reductions in competition due to foreclosure would likely be even more problematic. This linkage between the 1995 merger and the foreclosure concern, however, appears to be a relatively tenuous basis for using the COPA to guard against foreclosure rather than existing antitrust laws that would also prohibit such conduct.

[49] This suggests, however, that the COPA's Physician Employment Cap may be targeting the wrong physicians: rather than limit MHS's employment of primary care physicians in Buncombe and Madison counties – physicians that are already typically admitting almost exclusively to Mission Hospital – the cap should perhaps apply instead to physicians in the outlying counties that are more likely to otherwise be admitting to Mission Hospital's rival hospitals.

[50] Consider, for example, data on the admitting patterns for the top 50 physicians at one of Mission Hospital's local hospital rivals. These physicians, who collectively accounted for approximately 99 percent of all inpatient admissions at that hospital, made *no* admissions to Mission Hospital. Absent admissions to Mission Hospital, MHS is unlikely to have significant leverage over those physicians.

[51] See "Trauma Center," *Business North Carolina*, April 2010 and "Mission Exit Reflects Trend," *Asheville Citizen-Times*, November 1, 2009.

with other health care providers.[52] At least one payer I spoke to indicated that many physician practices in the WNC region were likely to be acquired in the future – either by a larger physician group, another hospital, or another health system (e.g., Novant Health or the Carolinas Healthcare System). A view was expressed that, of all these possible suitors for a physician practice, MHS might be the most desirable.

Second, preventing MHS from acquiring certain physician practices will reduce physicians' options. In some cases, this may mean that physicians leave the region (or decide not to come to the region in the first place). For physicians intent on selling their practice, the elimination of MHS as a potential bidder for that practice may significantly reduce the value that physicians receive for their practice.

Third, the Physician Employment Cap may preclude MHS from bringing new physicians to town. Bringing new physicians to town, however, is the type of output expansion that is likely to be procompetitive. The current Physician Employment Cap, however, would prohibit such recruitment of new physicians if it ended up pushing MHS over the 20 percent cap.[53]

Perhaps most important, to the extent that MHS can successfully integrate its acquired physicians in a way that will lower overall healthcare costs and increase quality, then preventing MHS from acquiring those physician practices could end up denying consumers the benefits of lower prices and better outcomes.[54]

D. Balancing likely benefits and harm from the Physician Employment Cap

Balancing the potentially significant downsides to the Physician Employment Cap against the weak merger-related justifications, I recommend that the Physician Employment Cap be dropped from the COPA.

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[52] According to the American Hospital Association, 65 percent of community hospitals are making efforts to increase the number of employed physicians. See "The State of America's Hospitals – Taking the Pulse, Results of AHA Survey of Hospital Leaders," March/April 2010, The American Hospital Association.

[53] The COPA contains provisions by which MHS can appeal the cap (see Section 8.3 of the COPA). Yet, even if an appeal were possible, the need to go through the appeal process likely constitutes a significant disincentive to pursue such physician recruitment.

[54] See, for example, articles co-authored by MHS's new CEO, Ronald A. Paulus, M.D., that describe benefits that he helped to achieve at the Geisenger Clinic which pursued an active strategy of physician integration ("Continuous Innovation In Health Care: Implications Of The Geisinger Experience," Ronald A. Paulus, Karen Davis, and Glenn D. Steele, *Health Affairs*, Volume 27, Number 5, September/October 2008, pages 1235 to 1245; "How Geisinger's Advanced Medical Home Model Argues The Case For Rapid-Cycle Innovation," Ronald A. Paulus et al., *Health Affairs*, November 2009, pages 2047 to 2053; "ProvenCare - A Provider-Driven Pay-for-Performance Program for Acute Episodic Cardiac Surgical Care," Ronald A. Paulus et al., *Annals of Surgery*, Volume 246, Number 4, October 2007, pages 613 to 623; "The Electronic Health Record and Care Reengineering: Performance Improvement Redefined, Ronald A. Paulus et al., Redesigning the Clinical Effectiveness Research Paradigm: Innovation and Practice-Based Approaches: Workshop Summary, National Academy of Sciences, 2010, pages 221 to 265; "Value and the Medical Home: Effects of Transformed Primary Care," Ronald A. Paulus et al., *The American Journal of Managed Care*, Volume 16, Number 8, August 2010, pages 607 to 615.).

Should the Physician Employment Cap be retained, however, the State should consider adjusting that cap in a number of regards, including expanding the scope (both with respect to covered specialties and covered geographies), and allowing for exceptions relating to single-practice physician groups or for physicians that move into the Asheville area. The State should also require additional documentation by which MHS demonstrates its compliance with this aspect of the COPA regulation.

E. Other laws limit hospitals' ability to employ physicians

Dropping the Physician Employment Cap from the COPA will not leave MHS free to acquire as many physician practices as it likes. Rather, even though no longer subject to the COPA's restrictions, MHS will be subject to the same regulatory and legal constraints facing any other party with respect to acquiring competing physician practices.[55]

The extent to which MHS can acquire more physician practices without running afoul of existing antitrust laws will depend on the extent to which MHS can show that the likely benefits of such acquisitions will outweigh the likely competitive harm.[56] MHS can then decide for itself whether to increase its share of physicians above 20 percent of the market, with that decision based in part on whether it believes such acquisitions will prompt an antitrust investigation and its expectations about the likely outcome of any such investigation.

[55] I assume that MHS will not be able to avoid such constraints by claiming some type of State Action exemption.

[56] See, for example, The U.S. Department of Justice/Federal Trade Commission 1996 *Statements of Antitrust Enforcement Policy in Health Care.* The potential costs and benefits of allowing greater physician concentration are also actively being debated in the context of policy discussions about Accountable Care Organizations ("ACOs") See, for example, the October, 2010 volume of *Competition Policy International*, including the following articles: Braun, C., "Clinical Integration: The Balancing of Competition and Health Care Policies;" Fischer, A. and Marx, D., "Antitrust Implications of Clinically-Integrated Managed Care Contracting Networks and Accountable Care Organizations;" and Vistnes, G., "The Interplay Between Competition and Clinical Integration: Why the Antitrust Agencies Care About Medical Care."

Table 1: Mission Hospital County-Level Market Shares Over Time in Western North Carolina

	Total Patient Count in 2009*	Mission Hospital's Share of Patients					
		2005	2006	2007	2008	2009	1st Half 2010
Buncombe	26,045	86.3%	86.9%	87.3%	87.8%	89.6%	90.5%
Henderson	12,740	22.1%	22.7%	23.8%	25.3%	29.6%	36.4%
Burke	10,548	5.3%	5.7%	5.8%	6.1%	5.8%	5.8%
Rutherford	8,613	5.9%	6.3%	6.7%	8.0%	7.2%	7.2%
Haywood	8,298	28.7%	27.2%	28.4%	35.9%	33.5%	32.8%
McDowell	5,131	31.5%	33.3%	32.9%	34.4%	37.8%	35.8%
Jackson	3,807	17.5%	21.1%	21.5%	24.5%	27.3%	28.8%
Macon	3,734	27.5%	31.0%	27.8%	31.0%	29.3%	29.6%
Transylvania	3,523	32.1%	32.4%	32.0%	35.4%	34.6%	35.8%
Cherokee	2,671	18.8%	17.9%	20.0%	19.2%	18.5%	19.8%
Swain	2,494	22.7%	21.6%	24.4%	26.2%	26.8%	23.7%
Yancey	2,329	45.5%	49.4%	48.6%	47.5%	50.2%	49.5%
Madison	2,172	88.9%	89.9%	88.5%	89.7%	90.8%	91.2%
Mitchell	2,138	27.4%	29.1%	28.0%	25.7%	28.1%	29.6%
Polk	1,790	11.9%	15.7%	14.5%	17.2%	16.6%	18.0%
Graham	1,116	22.3%	26.6%	24.4%	26.4%	27.5%	29.2%
Clay	916	20.8%	20.4%	20.2%	19.7%	21.4%	21.6%

Note:
* Total Patient Count represents the number of patients that reside in the county.

Sources:

Patient Shares 2005 to 2008: Second Amended and Restated Certificate of Public Advantage Periodic Report, September 30, 2009, Mission Hospital, Inc.

Patient Shares 2009 to June 2010: Thompson Reuters, Inpatient Data for North Carolina.

Table 2: Short-Term Acute Care and Critical Access Hospitals In Western North Carolina

Hospital Name	County	City	Hospital Type	Beds	Average Patients Per Day	# of Physicians Actively Admitting Patients*	Distance in Miles from Mission Hospital
Mission Hospital	Buncombe	Asheville	Acute Care	728	522	342	0
The McDowell Hospital	McDowell	Marion	Acute Care	49	16	16	35
Blue Ridge Regional Hospital	Mitchell	Spruce Pine	Acute Care	49	22	28	51
Transylvania Community Hospital	Transylvania	Brevard	Critical Access	35	17	22	29
Pardee Hospital	Henderson	Hendersonville	Acute Care	216	72	58	27
Murphy Medical Center	Cherokee	Murphy	Acute Care	190	27	22	111
Grace Hospital	Burk	Morganton	Acute Care	184	59	56	58
Rutherford Hospital	Rutherford	Rutherfordton	Acute Care	143	53	42	57
Valdese Hospital	Burk	Connellys Springs	Acute Care	131	27	26	65
Haywood Regional Medical Center	Haywood	Cylde	Acute Care	121	62	37	27
Highlands-Cashiers Hospital	Macon	Highlands	Critical Access	104	7	7	67
Park Ridge Hospital	Henderson	Hendersonville	Acute Care	98	43	42	15
Harris Regional Hospital	Jackson	Sylva	Acute Care	86	43	33	47
Saint Luke's Hospital	Polk	Columbus	Critical Access	35	15	5	39
Angel Medical Center	Macon	Franklin	Critical Access	25	17	16	69
Swain County Hospital	Swain	Bryson City	Critical Access	24	6	6	66

Notes:

* An active physician is defined as any physician with at least 12 admissions in the 12-month period ending June 30, 2010 based on State Inpatient data provided by Thompson Reuters.

The Asheville VA Medical Center and the Cherokee Indian Hospital have been excluded from the table because these facilities are primarily government funded.

Sources:

American Hospital Directory (ahd.com), November 8, 2010.

Thompson Reuters, Inpatient Data for North Carolina.

Table 3: The COPA's Cost Cap Methodology - Illustrative Example

Base Case

	Volume	"Price" per procedure	Total Revenue	Cost per Procedure	Total Cost
Inpatient Procedures	1,200	1,000	1,200,000	800	960,000
Outpatient Procedures	800	500	400,000	400	320,000
TOTAL			1,600,000		1,280,000
"Equivalent Outpatient Discharges"	400	1,000			
"Total Adjusted Discharges"	1,600				
"Cost/Adjusted Patient Discharge"	800				

20% Increase in Outpatient Price

	Volume	"Price" per procedure	Total Revenue	Cost per Procedure	Total Cost
Inpatient Procedures	1,200	1,000	1,200,000	800	960,000
Outpatient Procedures	800	**600**	480,000	400	320,000
TOTAL			1,680,000		1,280,000
"Equivalent Outpatient Discharges"	480	1,000			
"Total Adjusted Discharges"	1,680				
"Cost/Adjusted Patient Discharge"	762				

20% Increase in Outpatient Price and Volume

	Volume	"Price" per procedure	Total Revenue	Cost per Procedure	Total Cost
Inpatient Procedures	1,200	1,000	1,200,000	800	960,000
Outpatient Procedures	**960**	**600**	576,000	400	384,000
TOTAL			1,776,000		1,344,000
"Equivalent Outpatient Discharges"	576	1,000			
"Total Adjusted Discharges"	1,776				
"Cost/Adjusted Patient Discharge"	757				

Table 4: Mission Health System Operating Income
For the year ending September 30, 2009

	Total Revenue	Operating Income	Operating Income Margin
	($000)	($000)	
Mission Health Inc.	897,742	40,391	4.5%
Individual Components of Mission Health Inc.:			
Mission Hospital, Inc.	805,191	41,281	5.1%
McDowell Hospital, Inc.	33,980	(2,080)	(6.1%)
Blue Ridge Regional Hospital, Inc.	39,410	530	1.3%
Other	19,161	660	3.4%

Source:
Mission Health System, Inc. and Affiliates, Combined Financial Statements and Schedules, September 30, 2009 and 2008, KPMG, page 32.

Appendix

GREGORY S. VISTNES

Vice President

Ph.D. Economics,
Stanford University

M.A. Economics,
Stanford University

B.A. Economics,
University of California at
Berkeley (with High Honors)

Dr. Vistnes is an antitrust and industrial organization economist who works in a broad array of industries, including financial services, insurance, defense and aerospace, medical equipment, chemicals, software, energy, pharmaceuticals, steel, and various retail and industrial products. Dr. Vistnes is also an expert in the healthcare industry where he has frequently testified, published, and spoken at professional conferences.

In the course of his work, Dr. Vistnes regularly presents his analyses to the U.S. Department of Justice (DOJ) and the U.S. Federal Trade Commission (FTC). He also provides economic analyses for clients involved in private antitrust litigation, for clients involved in matters before state attorney generals, and for firms interested in anticipating the competitive implications of alternative strategies. Dr. Vistnes has also provided expert testimony in a variety of antitrust matters, both on behalf of private sector firms and government antitrust agencies.

Prior to joining CRA International, Dr. Vistnes was the Deputy Director for Antitrust in the Federal Trade Commission's Bureau of Economics. In that position, he supervised the FTC's staff of approximately 40 Ph.D.-level antitrust economists and directed the economic analysis of all antitrust matters before the FTC. Before that, he served as an Assistant Chief in the Antitrust Division of the U.S. Department of Justice. At both the FTC and DOJ, Dr. Vistnes headed analytical teams responsible for investigating pending mergers and acquisitions or alleged anticompetitive behavior. As part of his duties, he regularly advised key agency decision makers, including FTC commissioners and the Assistant Attorney General for Antitrust.

REPRESENTATIVE PROJECTS AND INDUSTRY EXPERTISE

- *Real Estate.* Dr. Vistnes served as the testifying expert for the DOJ in their multi-year litigation *U.S. v. National Association of Realtors* (NAR) regarding NAR's rules on how real estate brokers could use the Internet to compete. Dr. Vistnes has also testified before several states regarding competition the title insurance industry, and worked on several mergers (e.g., *Fidelity/LandAmerica*) involving title insurance providers.

- *Aftermarkets.* Dr. Vistnes testified before a jury in the *Static Control Components v. Lexmark International* litigation relating to replacement toner cartridges for laser printers. The jury agreed with Dr. Vistnes' opinion that the evidence showed that the aftermarket of replacement toner cartridges was the appropriate relevant market.

- *Insurance and Financial Services.* Dr. Vistnes has testified and provided analyses to both state and federal competition authorities regarding mergers of both insurance carriers (e.g., *MetLife/Travelers*) and insurance brokers (e.g., *Aon/Benfield*). Dr. Vistnes has also analyzed price fixing claims regarding initial public offerings (IPOs) and private equity firms.

- *Healthcare and Medical Products and Equipment.* Dr. Vistnes has provided court testimony and economic analyses relating to hospital mergers, hospital certificate of need applications, health plan mergers, and physician conduct. He has also provided analyses and testimony related to mergers and conduct issues relating to MRI providers, medical products and equipment, and medical technology.

- *Computer Software and Technology.* Dr. Vistnes has provided economic analyses in several software mergers that helped the merging parties avoid a second request by the government. Examples include matters involving software that provides security for internet websites; billing software used by large health plans; and the provision of electronic business-to-business services between trading partners.

- *Energy.* Dr. Vistnes has provided economic analyses of several antitrust matters in different sectors of the energy industry, including the oil, electricity, gas pipelines and gas storage sectors. In addition to overseeing the FTC's economic analyses of mergers such as *BP/Arco* and *Mobil/Exxon*, Dr. Vistnes has also presented his analyses to the Department of Justice regarding price fixing claims in this industry.

- *Price Fixing Cases.* Dr. Vistnes has provided analyses and reports regarding price fixing cases in the chemicals industry. Dr. Vistnes' work in these matters helped to determine the relevant scope of products affected by the alleged conspiracy, the time periods over which price effects may have arisen, and the magnitude of any damages associated with the conspiracy. Dr. Vistnes' work in this area has been used both in presentations to the Department of Justice and in private litigation.

PROFESSIONAL EXPERIENCE

2000–Present *Vice President*, CRA International, Washington, D.C.

Dr. Vistnes' work focuses on analyzing antitrust and competition issues such as:

- Horizontal and vertical mergers;
- Contractual provisions such as exclusivity provisions, most favored customer clauses, bundling provisions, and price discount schedules;
- Intellectual property and antitrust;
- Price fixing and conspiracy allegations;
- Class action litigation.

1997–2000 *Deputy Director for Antitrust*, Bureau of Economics, U.S. Federal Trade Commission, Washington, D.C.

- Directed the economic analyses of all antitrust matters before the Commission.
- Briefed Commissioners and the Director of the Bureau of Economics regarding all antitrust matters before the Commission, including mergers, vertical restraints, and joint ventures.
- Advised the Commission on whether to challenge mergers or other anticompetitive activities.
- Developed strategies for the investigation and litigation of antitrust matters before the Commission.
- Directed the FTC's antitrust staff of 55 Ph.D. economists, managers, and support staff.

1996–1997 *Assistant Chief*, Economic Regulatory Section, Antitrust Division, U.S. Department of Justice, Washington, DC.

- Directed economic analyses at the Antitrust Division in the health care and telecommunications industries;
- Briefed the Assistant Attorney General and Deputies on the economic aspects of health care and telecommunications matters;
- Played a key role in writing the 1996 Department of Justice/Federal Trade Commission's Statements of Antitrust Enforcement Policy in the Health Care Area;
- Led the Antitrust Division's economic analyses of hospital and HMO mergers and/or joint ventures in the health care industry;
- Directed the economic analyses of Bell Operating Company mergers;
- Headed DOJ's economic assessment of the conditions under which Bell Operating Companies should be allowed to enter into long-distance markets;
- Directed the economic analyses of the wave of radio station mergers following passage of the 1996 Telecommunications Act.

1995–1996 *Manager*, Health Care Issues Antitrust Division, U.S. Department of Justice, Washington, DC.

- Directed the economic analyses of all health care matters at the Division.

1990–1995 *Staff Economist*, Antitrust Division, U.S. Department of Justice, Washington, DC.

- Analyzed antitrust and competition-related matters in the health care, entertainment, natural resources, and industrial machinery industries;
- Designated as the Antitrust Division's economic testifying expert in numerous hospital mergers;
- Analyzed hospital and HMO mergers, physician joint ventures, healthcare information exchanges, and physician/hospital affiliations and mergers;
- Played a key role in writing the 1993 and 1994 Department of Justice/Federal Trade Commission's *Statements of Antitrust Enforcement Policy in the Health Care Area*;
- Designated as DOJ's Economic Representative to President Clinton's 1993 White House Task Force on Health Care Reform.

1988–1990 *Economic Consultant*, Putnam, Hayes and Bartlett, Washington, DC.

- Analyzed health care matters;
- Wrote strategy reports for clients interested in directing the course of health care reform at the local and federal levels;
- Developed pricing methodologies to promote competition in the electric utility industry.

1987–1988 *Visiting Professor*, Department of Economics, University of Washington, Seattle.

- Taught graduate and undergraduate health care economics, industrial organization & strategic firm behavior, and intermediate price theory.

SELECTED INDUSTRY EXPERTISE

- Healthcare
- Chemicals
- Insurance
- Software
- Financial Markets
- Pharmaceuticals
- Supermarkets
- Aerospace and Defense
- Medical Equipment and Services
- Energy

ORAL TESTIMONY

Wendy Fleischman, et al. v. Albany Medical Center, et al., U.S. District Court, Northern District of New York (Case No. 06-CV-0765/TJM/DRH), July 2009 and January 2010. [Deposition testimony on behalf of plaintiff class]

Pat Cason-Merenda et al. v. Detroit Medical Center, et al., Eastern District of Michigan, Southern Division (Case No. 06-15601), April 2009. [Deposition testimony on behalf of plaintiff class]

Munich Reinsurance Group Application for the Acquisition of Control of Hartford Steam Boiler. Testimony before the Commissioner of Insurance of the State of Connecticut, March 2009. [Oral hearing testimony on behalf of Munich Reinsurance Group]

United States of America v. National Association of Realtors. U.S. District Court (Northern District of Illinois – Eastern Division), July 2007 and December 2007. [Deposition testimony on behalf of the U.S. Department of Justice]

Funeral Consumers Alliance, Inc., et al. v. Service Corporation International, et al.. U.S. District Court (Southern District of Texas), Civil Action 3H-05-3394, July 2007. [Deposition testimony on behalf of Funeral Consumers Alliance, Inc.]

Static Control Components v. Lexmark International. U.S. District Court (Eastern District of Kentucky at Lexington), June 2007. [Trial and deposition testimony on behalf of Static Control Components, Wazana Brothers International and Pendl Companies]

Saint Alphonsus Diversified Care, Inc. v. MRI Associates, LLP; and MRI Associates, LLP v. Saint Alphonsus Diversified Care, Inc. and Saint Alphonsus Regional Medical Center. District Court for the Fourth Judicial District of the State of Idaho, May 2007. [Deposition testimony on behalf of Saint Alphonsus Regional Medical Center]

Louisiana Municipal Police Employees' Retirement System, et al., v. Crawford, et al., and *Express Scripts, Inc. v. Crawford, et al.* Del. Ch., C.A., No. 2635-N and 2663-N, February 2007. [Deposition testimony on behalf of Caremark Rx, Inc.]

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Wal-Mart Stores v. *the Secretary of Justice of the Commonwealth of Puerto Rico.* U.S. District Court (District of Puerto Rico), December 2002. [Trial testimony on behalf of Wal-Mart]

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Yakima Valley Memorial Hospital v. Washington State Department of Health, U.S. District Court, Eastern District of Washington (Case CV-09-3032-EFS). Expert report submitted on behalf of Yakima Valley Memorial Hospitals, April 2010.

DAW Industries, Inc. v. Hanger Orthopedic Group and Otto Bock Healthcare, U.S. District Court, Southern District of California (Case 06-CV-1222 JAH (NLS)). Expert report submitted on behalf of Otto Bock Healthcare, May 2009.

Hometown Health Plan, et al., vs. Aultman Health Foundation, et al., Court of Common Pleas, Tuscarawas County, OH (Case No. 2006 CV 06 0350). Expert report submitted on behalf of Hometown Health Plan, March 2008.

Texas Title Insurance Biennial Hearing, Docket Nos. 2668 and 2669. Pre-filed direct testimony on behalf of Fidelity National Financial, Inc., January 2, 2008.

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The St. Paul Companies/Travelers Property and Casualty Corp Merger. Expert report on behalf of St. Paul and Travelers, submitted to the California Department of Insurance, February 2004.

Granite Stone Business International (aka Eurimex) v. Rock of Ages Corporation. International Court of Arbitration, ICC Arbitration No. 11502/KGA/MS. Expert reports submitted on behalf of Granite Stone Business International, October 2002 and March 2003.

General Electric/Honeywell Merger. Expert reports (co-authored with Carl Shapiro and Patrick Rey) on behalf of General Electric, submitted to the U.S. Department of Justice and the European Commission, 2001.

United States and State of Florida v. Morton Plant Health System, Inc., and Trustees of Mease Hospital. U.S. District Court (Middle District of Florida – Tampa Division). Expert report on behalf of the U.S. Department of Justice, May 1994.

SELECTED PRESENTATIONS

"Interpreting Evidence Regarding Price Effects in Consummated Mergers," ABA Spring Meetings, Washington, DC, April 2010.

"Are There Different Rule of Reason Tests for Vertical and Horizontal Conduct?" ABA Joint Conduct Committee, teleconference presentation, June 2009.

"The Economics of Information Sharing and Competition," ABA Section on Business Law, Vancouver, BC, April 2009.

"United States versus the National Association of Realtors: The Economic Arguments and Implications for Trade Associations," ABA Spring Meetings, Washington, DC, March 2009.

"The Use of Price Effects Evidence in Consummated Merger Analysis," ABA Section of Antitrust Law, teleconference presentation, February 2009.

"Competition in the Title Insurance Industry – An Economic Analysis." National Association of Insurance Commissioners, Washington, DC, June 2006.

"Antitrust Issues in the BioTech Industry." Biotech Industry Organization BIO 2005 International Meetings, Philadelphia, June 2005.

"Cartels and Price Fixing – Ensuring Consistency Between Theory and the Facts." The Use of Economics in Competition Law, Brussels, January 2005.

"Intellectual Property and Antitrust in High-Tech Industries." ABA Section on Business Law, Atlanta, August 2004.

"Antitrust, Intellectual Property and Innovation." Biotech Industry Organization BIO 2004 International Meetings, San Francisco, June 2004.

"Quality, Healthcare and Antitrust." Petris Center/UC Berkeley Conference on Antitrust and Healthcare, University of California at Berkeley, April 2004.

"Unilateral Effects - Be Careful What You Wish For." Second Annual Merger Control Conference, The British Institute of International and Comparative Law, London, December 2003.

"Geographic Market Definition in Hospital Antitrust Analysis – Theory and Empirical Evidence." Federal Trade Commission/Department of Justice Joint Hearings on Health Care and Competition Law and Policy, Washington, DC, March 2003.

"Trade Barriers and Antitrust: Foreign Firms – Down But Not Out." Antitrust Issues in Today's Economy, The Conference Board, New York City, March 2003.

"Bundling and Tying: Antitrust Analyses in Markets with Intellectual Property." Department of Justice/Federal Trade Commission Joint Hearings on Intellectual Property and Antitrust, Washington, DC, May 2002.

"Practical Issues in Intellectual Property Investigations: Balancing Rules versus Discretion." Department of Justice/Federal Trade Commission Joint Hearings on Intellectual Property and Antitrust, Washington, DC, May 2002.

"Bundling and Tying: Recent Theories and Applications." Antitrust Section of the American Bar Association Meeting, Washington, DC, April 2002.

"Antitrust Issues in the Pharmaceutical Industry: The Hatch-Waxman Cases." ABA Healthcare and Intellectual Property Sections Brownbag, Washington, DC, February 2002.

"The GE/Honeywell Deal: Is Europe Raising the Yellow Flag on Efficiencies?" CRA Conference on Current Topics in Merger and Antitrust Enforcement, Washington, DC, October 2001.

"Marching to the Sounds of the Cannon: Antitrust Battlegrounds of the Future." National Association of Attorneys General Conference, San Diego, October 2000.

"The Joint Venture Guidelines: Navigating Outside the Safety Zones." The 8th Annual Golden State Antitrust and Unfair Competition Law Institute, Los Angeles, October 2000.

"Strategic Behavior in the Pharmaceutical Industry: The Hatch-Waxman Act and Blockading Entry." Antitrust Section of the American Bar Association Meeting, Washington, DC, April 2000.

"Working With Economic Experts." Antitrust Common Ground Conference, Chicago, IL, December 1999.

"Merger Enforcement Trends." CRA Conference on Current Topics in Merger and Antitrust Enforcement, Washington, DC, December 1998.

"Hot Topics in Health Care Antitrust." Antitrust Fundamentals for the Health Care Provider, Sponsored by the Wisconsin Field Office of the Federal Trade Commission, the US Department of Justice, and Marquette University Law School, Milwaukee, WI, December 1998.

"Federal Antitrust Enforcement in the Health Care Industry: New Directions." Fourth Annual Health Care Antitrust Forum, Northwestern University, September 1998.

"Hospital Competition in HMO Networks." American Economic Association Meetings, San Francisco (1996) and Chicago (1998).

"Creating Competitive Markets Amidst Barriers to Entry." Weeklong Presentation to the Russian State Committee of Antimonopoly Policy, Volgograd, Russia, January 1997.

"The Economics of Antitrust Law." Maine Bar Association, January 1995.

"The Competitive Impact of Differentiation Across Hospitals." Fourth Annual Health Economics Conference, Chicago, 1993.

"Multi-Firm Systems, Strategic Alliances, and Provider Integration." Pennsylvania State University, the University of California at Santa Barbara, and the Johns Hopkins School of Public Health, 1992 and 1993.

PUBLICATIONS

"Presumptions, Assumptions and the Evolution of U.S. Antitrust Policy." With Andrew Dick. *Trade Practices Law Journal*, December 2005.

"Commentary: Is Managed Care Leading to Consolidation in Health Care Markets?" *Health Services Research*, June 2002.

"Employer Contribution Methods and Health Insurance Premiums: Does Managed Competition Work?" With Jessica Vistnes and Phillip Cooper. *The International Journal of Health Care Finance and Economics*, 2001.

"Hospital Competition in HMO Networks: An Empirical Analysis of Hospital Pricing Behavior." With Robert Town. *The Journal of Health Economics*, September 2001.

"Hospitals, Mergers, and Two-Stage Competition." *The Antitrust Law Journal*, January 2000.

"Defining Geographic Markets for Hospital Mergers." *Antitrust*, Spring 1999.

"The Role of Third Party Views in Antitrust Analysis: Trust But Verify." *Government Antitrust Litigation Advisory*, American Bar Association, July 1998.

"Hospital Mergers and Antitrust Enforcement." *The Journal of Health Politics, Policy and Law*, Spring 1995.

"An Empirical Investigation of Procurement Contract Structures." *The Rand Journal of Economics*, Summer 1994.

PROFESSIONAL ACTIVITIES

Referee for:

- *The American Economic Review*
- *The Antitrust Law Journal*
- *Health Services Research*
- *Inquiry*
- *The Journal of Industrial Economics*
- *The Rand Journal of Economics*
- *The Review of Industrial Organization*

Grant Reviewer for:

- Robert Wood Johnson Foundation/Academy Health
- The Alpha Center
- Agency for Health Care Policy and Research

HONORS AND AWARDS

- Named one of *Global Competition Review's* 2006 "Top Young Economists" (identifying the top 22 antitrust economists in the U.S. and Europe under the age of 45)
- Assistant Attorney General's Merit Award (1994), Antitrust Division, U.S. Department of Justice
- Distinguished Teaching Fellowship (1986), Department of Economics, Stanford University
- Academic Fellowship (1983–1984), Department of Economics, Stanford University
- Phi Beta Kappa (1983)

EXHIBIT

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SECOND AMENDED CERTIFICATE OF PUBLIC ADVANTAGE

This Second Amended Certificate of Public Advantage is issued, pursuant to N.C. Gen. Stat. § 131 E-192.5, to applicants Mission Hospitals, Inc. and Mission Health, Inc. The stated purpose for which the applicants seek a second amended Certificate of Public Advantage, or COPA, is to update the COPA to reflect changes in facts and circumstances, including the accomplishment or expiration of certain provisions of the COPA, and to provide better tools and mechanisms for oversight by the State.

BACKGROUND: On December 21, 1995, pursuant to N.C. Gen. Stat. § 131E-192.5, the North Carolina Department of Health and Human Services, with the consent of the North Carolina Attorney General, issued a revised Certificate of Public Advantage. That initial COPA concerned a cooperative agreement between Memorial Mission Hospital, Inc. and St. Joseph's Hospital to form Mission-St. Joseph's Health System, Inc. to serve as the "managing member" of both hospitals and to manage and operate the two hospitals as integrated entities.

The Hospitals and their managing member, Mission-St. Joseph's Health System, Inc., operated under the initial COPA for more than two and one-half years, with the active supervision of the Department and the Attorney General and in full compliance with the terms and conditions of the COPA, achieving the efficiencies, savings, and other benefits that the COPA contemplated. In 1998, the parties determined that it was in the best interests of the communities they served for Memorial Mission Hospital, Inc. to acquire St. Joseph's Hospital in a statutory merger of St. Joseph's Hospital with and into Memorial Mission Hospital, Inc. Following the transaction, the Mission-St. Joseph's Health System, Inc. became the sole owner and corporate member of Memorial Mission Hospital, Inc. that operated on the Mission and St. Joseph's campuses, on a fully integrated basis.

The First Amended COPA, issued on October 8, 1998, reflecting the conclusions of the Department of Health and Human Services, in consultation with the Attorney General, about the applicants' requested amendments, permitted the referenced merger.

As of December 1, 2003, Memorial Mission Hospital, Inc. changed its name to Mission Hospitals, Inc. and Mission-St. Joseph's Health System, Inc. changed its name to Mission Health, Inc.

I. Definitions

1. "Mission Health, Inc." refers to Mission Health, Inc., the successor in title to Mission St. Joseph's Health System, Inc., the entity created by Memorial Mission Hospital, Inc., and St. Joseph's Hospital to provide common management to both facilities, and later merged with and into Memorial Mission Medical Center, Inc., the name of which was then changed to Mission-St. Joseph's Health System, Inc.

2. "Attorney General" means the North Carolina Department of Justice, Attorney General's Office.

3. "Department" means the North Carolina Department of Health and Human Services.

4. "Service area" means and includes the area of Western North Carolina encompassing the following 17 counties: Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, and Yancey.

5. "State Agencies" means the Department of Health and Human Services and the Attorney General's Office.

6. " Mission Hospitals, Inc." is a tax-exempt nonprofit charitable organization that owns the Memorial and St. Joseph's hospital facilities in Asheville.

II. Advantages and Disadvantages of the Transaction

N.C. Gen. Stat. § 131E-192.4(b) lists the advantages and disadvantages which the Department must consider in reviewing a COPA application. Each statutory criterion is set forth below, and is followed by the Department's determination regarding it. In making its determinations regarding these criteria, and in establishing the conditions of this COPA (see Part III, below), the Department consulted with the Attorney General, and considered the application and materials submitted by the parties and all oral and written comments provided by others.

Potential Benefits

(1) Enhancement of the quality of hospital and hospital-related care provided to North Carolina citizens.

Mission Hospitals, Inc. is licensed and certified for participation in Title XVIII and XIX by the Division of Facility Services and accredited by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO).

10 NCAC 3C.109, entitled "Licensure Surveys," provides at subsection (c):

> Hospitals that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) shall choose one of the following options:
>
> (1) accredited hospitals may agree to provide the division with:
>
> (A) JCAHO Accreditation Certificate
> (B) JCAHO Statement of Construction
> (C) JCAHO Report and Recommendations
> (D) JCAHO Interim Self-Survey Reports, and
> (E) permission to participate in any regular survey conducted by the JCAHO.
>
> If a review of the information listed in Subparagraphs (c)(l)(A)-(c)(l)(D) indicates deficiencies with or exceptions to licensure regulations contained in this subchapter then the Division may conduct surveys or partial surveys with special emphasis on deficiencies noted.

The JCAHO accreditation process includes surveys that evaluate and rank the quality of care in several areas of hospital operations, including patient care. The JCAHO surveys are conducted at intervals of three years. Memorial Mission Hospital, Inc. was surveyed on June 16 through 20, 2003 and received accreditation for a three year period. All recommendations for improvement have been cleared.

Mission Hospitals, Inc. currently offers high-quality services according to the surveys and measurements available for assessing quality. In order to assure that the quality of hospital services are maintained the State Agencies will require, as more fully shown below, that there be no deterioration in quality according to surveys to be conducted by the Joint Commission on Accreditation of Healthcare Organizations.

Therefore, it is found that the quality of hospital and hospital related care provided to North Carolina citizens would likely be maintained or enhanced if the Terms and Conditions of this Second Amended Certificate of Public Advantage are met.

Potential Benefits

(2) Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities.

For the purposes of determining the impact of the proposed agreement, the Western North Carolina region for determining geographic proximity includes the following 17 counties: Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, and Yancey. Of these 17 counties, Clay, Graham, Madison, and Yancey have no acute care hospital within their borders. Within this region there are 16 acute care general hospitals one rehabilitation hospital and one long-term acute care hospital. There is also a Veterans Administration Hospital and healthcare facility in Asheville and a U.S. Public Health Service Hospital on the Cherokee Indian Reservation. The Mission Hospitals facility is the largest hospital in the region. The basis for including all 17 counties is that at least 38.4% percent of persons hospitalized for acute care services from these counties use Mission Health for acute care.

Mission Health dominates the market share in two counties. 93.8% of Madison County admissions and 90.6% of Buncombe County admissions are at Mission Hospitals' facilities, which are located in Buncombe County. Madison County, which has no hospital, is closer to Mission Hospitals in Asheville than to any other acute care hospital.

The State Agencies will conduct ongoing monitoring of hospital utilization and patient origin data throughout the area in order to determine if particular communities may experience a loss of geographical access to needed services. The State Agencies will then assess whether such a potential loss is related to the operation or activities of Mission Hospitals, Inc.

It is found that under the Second Amended COPA, Mission Health and Mission Hospitals will likely preserve hospital facilities in their dominant market and, will not likely cause a loss of hospitals in geographical proximity to the communities in the remainder of the service area, and will optimize the resources of Mission Health..

Potential Benefits

(3) Lower costs of or gains in the efficiency of delivering hospital services.

The original application for the Certificate of Public Advantage proposed cost savings as the primary benefit of the combination of hospital operations. Through the elimination of planned capital expenditures and a reduction of operating costs the Hospitals determined that at least $74.2 million could be saved over the first five years of operation.

In addition, the Hospitals proposed a cap on increases in charges. The cap would be based on an appropriate medical inflation index.

The savings proposed in the application demonstrated a substantial benefit of the combined operation and provided a basis for granting the COPA. The projected savings were arrived at through a study of the Hospitals by Arthur Andersen & Co.

Because the Hospitals did not want to be held to every recommendation made in the Arthur Andersen study, an ability to substitute items that would not diminish the total savings

was approved. In order to document the savings in such an environment, an independent consultant was employed to verify the savings on an annual basis over the five-year period.

It is important that the Hospitals both contain their costs and keep their operating margins reasonable when compared to other similar hospitals in North Carolina. To that end the Department will seek to limit and control the costs and operating margins of the hospital operations of the applicant.

It is therefore found that the savings accomplished by theHospitals and the monitoring and supervision by the State Agencies of costs and operating margins as provided in the Terms and Conditions of this Second Amended COPA will likely lead to a lowering of costs and increased efficiency of hospital services delivered in the area as a result of the combination.

Potential Benefits

(4) Improvements in the utilization of hospital resources and equipment

Mission Hospitals, Inc. has 735 licensed acute care beds, including 57 psychiatric beds.. Mission Hospitals is the only provider of open-heart surgery services in Buncombe County and the 17 county region in Western North Carolina. It is also the only hospital that has an in-patient dialysis unit in the region. Mission Hospitals is part owner of both Asheville Specialty Hospital, a long-term acute care facility, and the Asheville MRI Center. Mission Hospitals and the Asheville MRI Center both operate MRI scanners. Mission Hospitals has radiation therapy equipment (linear accelerators).

Under the initial COPA and the First Amended COPA, Mission Hospitals and Mission Health (and their predecessor entities) demonstrated improvements in the utilization of hospital resources and equipment, and it is found that the Second Amended COPA will permit the preservation and continuation of such improvements.

Potential Benefits

(5) Avoidance of duplication of hospital resources.

The initial agreement involved the consolidation of services that was to result in an estimated five-year net savings of $74,215,848. Savings were accomplished in four areas: (1) avoidance of capital expenditures, such as duplication of obstetric services and urology services, (2) reduction of positions, (3) employee benefits, and (4) efficiencies in operations. The total five year gross saving was projected to be $81.6 million. After deducting the cost of implementing the consolidation, the five-year net saving was projected to be about $74.2 million. Of the 167.5 positions identified for elimination between the two Hospitals, about 36% are management, 19% clerical, and 45% other hospital staff. As a result of the First Amended COPA the Hospitals committed to save an additional $2 million by the end of the five year period due to increased efficiencies Patient services to be consolidated included outpatient imaging, emergency/trauma services, and oncology services.

The initial agreement also involved making operations more efficient by consolidating duplicate functions in the areas of Administration, Accounting/Finance, Business Office, Human Resources, Planning and Communications, Information Services, Materials Management/ Purchasing, Nursing Administration, Laboratory, and Outpatient Services. In other areas only management was consolidated, including Medical Records, Plant Services, Housekeeping, Dietary/Cafeteria/Vending, Quality Assurance, Cardio/Respiratory Services, Pharmacy, and Rehabilitation Services. Other types of collaboration strategies were proposed in the areas of Medical/Surgical Floors, Intensive/Critical Care, Surgical Services, Emergency Services, Primary Care Network, and Radiology.

The proposed savings were accomplished and it is therefore found that the Hospitals adequately demonstrated that the proposed merger allowed the two facilities to avoid unnecessary duplication of hospital resources.

Potential Benefits

(6) The extent to which medically underserved populations are expected to utilize the proposed services.

The initial application from the Hospitals did not suggest that any restriction of services to Medicare or Medicaid patients was under consideration. Indeed, at present Mission Hospitals relies on these programs to provide payment for most of its patients. Slightly more than 68% of the inpatient gross revenue and approximately 43% of the outpatient gross revenue for Mission Hospitals comes from these programs.

Mission Health provides significant amounts of care to uninsured and underinsured patients. It has well-established policies for providing such care, with patients determined eligible for free or reduced price care based on their income and policies for writing off debt as uncollectible. Care represented by such debt is then counted in calculating total amounts of charity care.

Mission Hospitals issued a 2004 Community Benefits Report that shows dollars invested in community benefits having increased from $42,723,492 in 1997 to $69,714,024 in 2003. These figures include charity care, donations to community services, free health services like screenings and immunizations, costs the government does not cover treating Medicare and Medicaid patients, and other non-cash reimbursed services.

Nothing in the application for a second amended COPA suggests any attempt to eliminate or reduce the amount of care provided to uninsured, underinsured, and otherwise indigent patients.. Mission Hospitals helps to support a clinic to provide medical care to indigent patients in an underserved neighborhood and supports The Asheville Buncombe Community Christian Ministry Clinic to provide additional services.

Merging hospital operations has provided increased capacity to serve the underserved population with no reduction in the commitment to do so. In the past it has been pursuit of a mission, not competition that has led to Mission Health's providing care to the underserved. Under the conditions of this Second Amended COPA, the merged entity should provide continued access to care by underserved populations.

It is therefore found that medically underserved populations are likely to continue to benefit from the proposed merger.

Potential Disadvantages

(1) The extent to which the agreement may increase costs or prices of health care at a hospital which is party to the cooperative agreement.

The stated purpose of the initial proposal to combine operation of the two Hospitals was to reduce costs and contain charges. Because reduced competition could have the opposite effect, the State Agencies established a method to monitor and supervise the costs and operating margins of the Hospitals to assure that they do not exceed those of comparable hospitals.

The entity will be required to show that its increase in cost per adjusted patient discharge is no more than the Producer Price Index for general medical and surgical hospitals and that its operating margin does not exceed the mean of the selected other comparable institutions over any three-year period.

It is therefore found that as conditioned elsewhere in this Agreement the proposed merger of the Hospitals will not likely have an adverse effect on costs or prices of health care.

Potential Disadvantages

(2) The extent to which the agreement may have an adverse impact on patients in the quality, availability, and price of health care services.

Conditions and terms of this Second Amended COPA are specifically designed to address the quality, availability and prices of health care service provided at the applicant institutions.

The stated purpose of both the initial application and the applications for amendment is to reduce costs which will in turn affect the price of services. While some duplication of services will continue to be eliminated, there are no stated plans to eliminate any services. Mission Hospitals is explicitly required to maintain quality as part of the conditions of this agreement.

It is therefore found that as conditioned the merger of the Hospitals will not likely have an adverse impact on patients in the quality, availability and price of health care services.

Potential Disadvantages

(3) The extent to which the agreement may reduce competition among the parties to the agreement and the likely effects thereof.

The combination of operations of Memorial Mission and St. Joseph's Hospitals, the two largest acute care facilities in Asheville and its surrounding environs, has reduced competition. While the two Hospitals did not compete in all areas of services, there was substantial overlap of the services they provide.

The effects of the reduced competition, however, were designed to lower costs and maintain the availability of services presently offered. While there has been some consolidation of services and a reduction of duplication, no services have been eliminated.

Maintenance of services at lower costs should not adversely impact the patient population served by the Hospitals even though there is reduced competition. The terms and conditions of the Certificate of Public Advantage, the First Amended Certificate of Public Advantage and now the Second Amended Certificate of Public Advantage are designed to assure that the beneficial effects of the arrangement will materialize.

It is therefore found that the reduced competition brought about by the proposed merger, within the framework of the terms and conditions of this Second Amended Certificate of Public Advantage, will likely benefit the consumers of hospital services in the area.

Potential Disadvantages

(4) The extent to which the agreement may have an adverse impact on the ability of health maintenance organizations, preferred providers organizations, managed health care service agents, or other health care payors to negotiate optimal payment and service

arrangements with hospitals, physicians, allied health care professionals, or other health care-providers.

The merger, as conditioned by the First Amended COPA, should not significantly impact the ability of managed care providers and payors to negotiate optimal arrangements for several reasons:

1) The Hospitals did not effectively compete with one another before issuance of the COPA for such contracts because St. Joseph's did not offer enough services to make exclusive contracting practical.

2) Competition for tertiary care services currently exists and will continue to exist from points around Asheville such as Charlotte; Johnson City, Tenn.; Greenville/Spartanburg S.C.; and Atlanta, Ga.

3) The primary objective of the merger and the main focus of state supervision is a reduction of costs. In addition, supervision will assure that operating margins are reasonable.

The ability of managed care providers and payors to contract with physicians, allied health professionals and other health care providers will not be changed as a result of the proposed merger so long as the merged facility does not establish employment or exclusive dealing arrangements with physicians and allied health professionals in the primary service area above the limits established in this Second Amended COPA.

This finding therefore concludes that the merger does not significantly affect the ability of managed care providers to negotiate with Mission Hospitals and that the terms and conditions of the Second Amended COPA will adequately protect the ability of managed care providers and payors to negotiate reasonable arrangements.

Potential Disadvantages

(5) The extent to which the agreement may result in a reduction in competition among physicians, allied health professionals, other health care providers, or other persons furnishing goods or services to, or in competition with hospitals.

There seems to be no basis to conclude that competition among physicians, allied health professionals or other health care providers will be significantly different as a result of this Second Amended COPA

The State Agencies have reviewed and conditioned the exclusive physician provider contracts of Mission Hospitals and will continue to monitor the terms of such contracts.

Others furnishing goods or services to Mission Hospitals will continue to compete with one another on the basis of cost, quality and service. .

This finding therefore concludes that the Second Amended COPA under consideration in this application is not likely, on balance, to result in a disadvantage due to reduced competition among various health care providers or other persons furnishing goods and services to or in competition with them.

Potential Disadvantages

(6) The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to and reduction in competition.

. The Second Amended COPA does not raise any potential disadvantages not already considered in the COPA or the First Amended COPA.

III. Terms and Conditions of Second Amended COPA

Following are the terms and conditions upon which this Second Amended COPA is issued:

(1) Accreditation of Mission Hospitals, Inc. Mission Hospitals, Inc. shall:

1.1 Remain accredited by the Joint Commission for accreditation of Healthcare Organizations (JCAHO).

1.2 Not become conditionally accredited by the JCAHO.

1.3 Correct any requirements for improvement and/or supplemental findings from JCAHO surveys within the time frame set by the JCAHO.

1.4 Promptly provide to the State Agencies an explanation of requirements for improvement received in surveys, submit action plans to improve such deficiencies as part of the Interim or Periodic Report to the State Agencies, and attach copies of any focused survey results received from JCAHO.

1.5 Maintain a three-year JCAHO survey schedule for JCAHO surveys.

(2) Charity and Indigent Care.

2.1 The general policy of Mission Health, Inc. to provide needed health care services to those requiring such care regardless of their ability to pay shall be continued.

2.2 Medicare and Medicaid patients shall continue to enjoy access to all needed health services of the combined entity on the same basis as patients represented by any other payor.

2.3 The policy for the provision of charity care currently in effect at Mission Health, Inc. shall be used as the policy for providing such care.

(3) Purchase of Equipment and Supplies by Competitive Bidding. The purchase of equipment and supplies used at Mission Hospitals shall be made on a competitive basis to effectuate the lowest cost possible consistent with required quality, compatibility and efficiency.

(4) Controls on Costs and Margins.

4.1 Following the end of each fiscal year Mission Hospitals, Inc. shall provide to the State Agencies, in addition to its audited financial statements, the following accounting and statistical information: net in-patient revenue, net out-patient revenue, in-patient discharges, and the case-mix index for all acute care hospital in-patients. In addition, further breakouts of information contained in the audited financial statements shall be provided to the State Agencies or their designee upon request.

The Department of Health and Human Services or its designee will use the above information to develop a cost per adjusted patient discharge for Mission Hospitals, Inc. Cost per adjusted patient discharge shall be calculated as follows: 1) multiply inpatient discharges by case mix index to obtain case mix adjusted discharges; 2) divide inpatient revenue by case mix adjusted discharges to obtain revenue per inpatient discharge; 3) divide outpatient revenue by revenue per inpatient discharge to obtain equivalent outpatient discharges; 4) add case mix adjusted discharges and equivalent outpatient discharges to obtain total adjusted discharges; 5) divide operating expenses by total adjusted discharges to obtain cost per adjusted patient discharge.

Mission Hospitals, Inc. shall keep its cost per adjusted patient discharge to no more than the amount for the previous year, plus the product of that amount multiplied by the percentage increase, in the relevant year, in the Producer Price Index for general medical and surgical hospitals (PPI) as published by the United States Department of Labor. The following and each successive year the Hospital shall keep its cost per adjusted patient discharge to no more than the lesser of the above calculation or $6,000 multiplied by the 2004 Producer Price Index and in each successive year thereafter the product from the preceding year multiplied by the PPI for the relevant year.

A failure of Mission Hospitals, Inc. to keep its cost per adjusted patient discharge at or below the requirement set out in the previous paragraph for two consecutive

years shall result in Mission Hospital Inc. employing a management consultant approved by the Department to study and recommend actions to reduce its costs to the required level. The State Agencies will provide Mission Hospital, Inc. the opportunity to comment on the consultant's recommendations, before making final recommendations to Mission Hospitals, Inc. Mission Hospitals, Inc. shall implement the recommendations made by the State Agencies.

The cost per adjusted discharge of Mission Hospitals, Inc. shall also be compared with similarly calculated costs of comparable hospitals. Comparable hospitals may be a selected group of hospitals of 300 beds or more excluding academic medical center teaching hospitals such as Duke University Health System, The North Carolina Baptist Hospitals, Inc., UNC Hospitals, and Pitt County Memorial Hospital, Inc. This comparison will be used by the state agencies to help them determine if the PPI seems to be an appropriate standard.

4.2 The Department of Health and Human Services will calculate the operating margin in fiscal years subsequent to 2003 of Mission Health, Inc. derived by dividing the excess of operating revenues over operating expenses by operating revenues.

The operating margin, expressed in percentage terms, of Mission Health, Inc. shall not exceed by more than one percent the mean of the median operating margins of hospitals rated in the AA, category by Standard and Poor's, the Aa category of Moody's Investor Service, and the AA category of Fitch Ratings over any three-year period, provided that in no event shall Mission Health, Inc. be required to have an operating margin of less than three percent. For purposes of applying this test the Hospital's excess for 2003 of $3,175,690 will be carried over into the Second Amended COPA for future calculations of the allowable margin for a three-year period.

To the extent that operating margins exceed the amounts set forth above, over any three-year period the total dollar difference between the amount realized and the amount allowed shall be deposited, according to a schedule established by the State Agencies, in a separate fund established by Mission Health, Inc. and directed by the State Agencies, provided that the State Agencies also determine that any required transfer in a given year will not result in either Mission Hospitals, Inc. or Mission Health, Inc. failing to meet financial ratios established by covenants for bonds issued on their behalf by the North Carolina Medical Care Commission. Mission Hospitals, Inc. and Mission Health, Inc. shall be jointly and severally liable for such amount. Money in this fund shall be used to support or provide low-cost or no-cost health-care services to residents of western North Carolina such as child immunizations, mammograms, drug and alcohol abuse treatment programs, or other health-care services needed by the community for which adequate resources are not available. The State Agencies may select, after receiving any input from Mission Health, Inc. one or more charitable organizations to utilize these funds. The selected organization(s) shall submit quarterly reports to the State Agencies on the expenditure of the funds. In the event of a settlement and deposit of funds representing excess margin as described above, a new three-year measurement period shall begin.

The operating margin of Mission Hospitals, Inc. will also be compared with similarly calculated operating margins of comparable hospitals selected by the Department in consultation with the Attorney General. Comparable hospitals may be a selected group of hospitals of 300 beds or more excluding academic medical center teaching hospitals such as Duke University Health System, The North Carolina Baptist Hospitals, Inc., UNC Hospitals, and Pitt County Memorial Hospital, Inc. This comparison will be used by the State Agencies to help them determine the appropriateness of the comparison with the median of AA rated facilities. The manner in which extraordinary items will be considered or adjusted will be determined on a case-by-case basis by Mission Health and the State Agencies.

4.3 The parties to this Second Amended COPA further stipulate and agree that the Department may, in its discretion and with the approval of the Attorney General, establish an alternative methodology or incentive designed to reflect competitive conditions to control Mission Hospitals, Inc. costs or operating margins following its review of the Periodic or Interim Reports described in subparagraphs 11.1 and 11.3 of this document.

4.4 Subparagraphs 4.1 through 4.3 shall apply only during those fiscal years when the State of North Carolina or the federal government does not substantially regulate hospital rates.

(5) Nonexclusivity.

5.1 Mission Health shall not enter into any provider contract with any health plan on terms that prohibit it from entering into a provider contract for any services it offers with any other health plan.

5.2 Mission Health shall not require managed-care plans to contract with its employed doctors as a precondition to contracting with it or its constituent hospitals.

5.3 Mission Health shall not restrict an independent physician's provision of services or procedures outside the member hospitals, unless performance of duties outside the member hospitals would impair or interfere with the safe and effective treatment of a patient.

5.4 Mission Health shall not prohibit independent physicians who are members in any Mission Health physician-hospital network from participating in any other physician-hospital network, health plan, or integrated delivery system.

(6) Nondiscrimination.

6.1 Except as provided herein, Mission Health shall not enter into any exclusive contract with any physician or group of physicians by which it requires that physician or group of physicians to render services only at Mission Hospitals, or by which it requires only one physician or group of physicians to provide particular services at Mission Hospitals. However, Mission Health may enter into exclusive contracts with anesthesiologists; radiologists; nuclear medicine physicians; pathologists; psychiatrists; emergency-room physicians; infectious disease physicians; neonatologists; nephrologists; pediatric subspecialists (e.g., pediatric cardiologists); perinatologists; pulmonologists; radiation oncologists; trauma surgeons; cardiologists; cardiovascular surgeons; neurologists; and physicians providing services in Mission Health's community access clinics. This provision, however, shall not require Mission Health to terminate any existing contracts, and Mission Health may continue to require its employed physicians to render services only at Mission Hospitals. Mission Health may also petition the State Agencies for approval to enter into exclusive contracts with physicians in specialties other than those above.

6.2 Other than as provided in Paragraph 8.1, and except as restrictions on granting certain medical privileges are necessary to maintain physicians' qualifications, including clinical competency, Mission Hospitals shall provide an open staff, ensuring equal access to all qualified physicians in, and in reasonable proximity to, Buncombe County, according to the criteria of the JCAHO and the medical staff by-laws.

6.3 Mission Health shall negotiate in good faith with all health plans with a service area or proposed service area within or including western North Carolina that approach it seeking a provider contract. This provision, however, shall not be construed to require Mission Health to enter into a provider contract with any particular health plan.

6.4 Mission Health shall not enter into a provider contract with any licensed health plan operated by Mission Health itself, in existence now or which may be created, on terms available to that plan solely because it is wholly-or-partially-owned, controlled or sponsored by Mission Health, where doing so would place other comparable licensed health plans at a competitive disadvantage because of any market power Mission Health may have rather than from efficiencies resulting from its integration with its health plan. However, this subsection 6.4 shall not apply to the provision of hospital services to employees of Mission Health or its affiliates.

6.5 With respect to any managed-care plan affiliated with or proposed by Mission Health or any other group or alliance of hospitals, Mission Health shall participate in such plan only on nonexclusive terms. Further, Mission Health shall not engage in any "most-favored-nation" pricing with respect to such a plan vis-a-vis other competing managed-care plans in its market, and shall not cross-subsidize any such plan through the operating revenues of Mission Health in a manner that would facilitate predatory pricing or other anticompetitive conduct.

(7) Health Plans

7.1 Mission Health shall not unreasonably terminate any provider contracts to which it or one of its member hospitals is party as of the date of issuance of the Second Amended COPA.

7.2 Mission Health shall attempt, in good faith, to contract with all health plans operating in its service area that offer commercially-reasonable terms on a fully-capitated basis, a percentage of premium revenue basis, or on other terms that require Mission Health to assume risk. Mission Health shall not refuse to contract with a health plan solely because such plan proposes a risk bearing or capitated contractual reimbursement methodology. This provision, however, does not require Mission Health to enter into a provider contract with any particular health plan or with all health plans.

(8) Employment of or Contracting with Physicians.

8.1 Notwithstanding Section 6.1, above, Mission Health may employ or enter into exclusive contracts with no more than 20% of the physicians in its primary service area of Buncombe and Madison Counties, practicing in any of the following areas: family practice/internal medicine, general pediatrics, or obstetrics/gynecology. This percentage limit shall apply to each such area of practice. In calculating this percentage, full-time residency faculty members employed by Mission Health and residents employed by MAHEC shall be included, and physicians whose primary employment is at Mission Health's community access clinics shall be excluded.

8.2 Mission Health shall not solicit the employment of any physician or group practice within its primary service area of Buncombe and Madison Counties if such employment would exceed the limitations imposed by Subparagraph 8.1.

8.3 Mission Health may petition the State Agencies in writing for an exception to Subparagraph 8.1 if market conditions warrant employing physicians in any of the enumerated categories above the 20% level. Market conditions potentially justifying an exception include providing physicians to an underserved area.

(9) "Most-Favored-Nation" Provisions in Contracts with Health Plans.

Mission Health shall not enter into any provider contract with any health plan on terms which include a "most-favored-nation" clause to the benefit of Mission Health or any health care plan. A "most-favored-nation" clause is any term in a provider contract that guarantees either party that it will receive the benefit of any better price, term or condition than the other party to the contract allows to a third person for the same service.

(10) Ancillary Services.

10.1 Patient referrals for durable medical equipment, home health services, or home infusion services made by Mission Health, its employees, contractors and medical staff shall provide for patient choice among the competitors in those markets and

shall be on a non-discriminatory basis without regard to whether Mission Health owns or operates the provider of such services.

10.2 Mission Health shall document that each patient referral for such services has been made in compliance with the preceding subparagraph 10.1.

10.3 If providers of ancillary services not affiliated with Mission Health cannot or do not provide such goods or services in a manner that would permit Mission Health to contain costs in the context of risk-bearing contracts, l Mission Health may petition the State Agencies for an exception to subparagraphs 10.1 and 10.2.

(11) Reports

11.1 Within four months from the close of the second fiscal year of each biennium during which the COPA and now the Second Amended COPA is in effect, Mission Health shall submit to the State Agencies a Periodic Report accompanied by an officer's compliance certificate describing its compliance with this COPA. The Periodic Reports shall address in detail:

1) Annual utilization of beds, equipment, and services and any increases or decreases in utilization of beds, equipment, and services;

2) Acute care hospital utilization for the 17-county Western North Carolina region. If a report, or the Department's own determination, indicates that the future survival of any one of the other general acute care hospitals in the region is in jeopardy, Mission Health will be requested to evaluate the situation and report to the Division of Facility Services whether the ability of persons to maintain access to general acute care services is in jeopardy. If persons in the region are in jeopardy of losing access to general acute care services, Mission Heath will be requested to present the Division of Facility Services with alternatives to address the needs of these persons; and

3) All funds that were provided during the preceding fiscal year by Mission Health to any managed care plan owned or controlled by it.

11.2 Mission Health shall notify the Division of Facility Services in advance if it is proposing to add or delete a health service.

11.3 Within four months from the close of each fiscal year during which first the COPA and now the Second Amended COPA is in effect, and in which Mission Health is not required to submit a Periodic report, Mission Health shall submit to the State Agencies an Interim Report accompanied by an officer's compliance certificate certifying its compliance with this Second Amended COPA. The next Interim Report shall be filed no later than January 31, 2006. This report shall address in detail:

1) The methods used to insure competitive prices of its purchases of equipment and supplies;

2) Acute care hospital utilization for the 17-county Western North Carolina region. If a report, or the Department's own determination, indicates that the future survival of any one of the other general acute care hospitals in the region is in jeopardy, Mission Health will be requested to evaluate the situation and report to the Division of Facility Services whether the ability of persons to maintain access to general acute care services is in jeopardy. If persons in the region are in jeopardy of losing access to general acute care services, Mission Health will be requested to present the Division of Facility Services with alternatives to address the needs of these persons; and

3) All funds that were provided during the preceding fiscal year by Mission Health to any managed care plan owned or controlled by it.

It is also stipulated and agreed that following their review of the Interim Report, the State Agencies shall have the same discretion to modify or

revoke the Second Amended COPA as the statute provides them with respect to the Periodic Report in N.C. Gen. Stat. § 131E-192.9.

11.4 The Department finds and concludes that: the proposed transaction has made more permanent and difficult to dissolve the combination of two complex organizations; that verification of the benefits of this Second Amended COPA to the public (and in particular the stated cost savings) is critical to assuring that the public benefits of this Second Amended COPA in fact exceed the public detriments due to the reduction in competition; and that the Department cannot include adequate "conditions to control prices of health care services provided under the [COPA]," N.C. Gen. Stat. § 131E-192.5, nor supervise compliance with these conditions sufficient to achieve for the merged entity the immunity that the General Assembly intended, N.C. Gen. Stat. § 131E-192.13(a), while also assuring that the costs of its oversight of the Second Amended COPA are fully supported by COPA application fees and periodic report fees, per N.C. Gen. Stat. § 131E-192.11. Therefore, in order to carry out the General Assembly's intent of assuring that the public interest is served, and of providing the merged entity immunity for conduct that serves the public interest, the Department can grant this Second Amended COPA only if Mission Health agrees, by consenting to this Second Amended COPA (per paragraph 18, below), to pay the Department, the Attorney General, or their designee(s), for annual expenses, including any expert fees, incurred in analyzing and verifying its Periodic and Interim Reports, in an amount not to exceed $25,000 per year (to be paid within thirty days of receiving the invoice(s) therefor).

11.5 Mission Health shall cooperate with the Department of Health and Human Services, the Attorney General, and any expert engaged by either agency or by Mission Health pursuant to this the COPA and now to this Second Amended COPA. Such cooperation shall include but not be limited to providing any additional requested information reasonably necessary to complete the analysis and verification of the compliance reports.

(12) Compliance. To determine or secure compliance with this Second Amended COPA, any duly authorized representative of the State Agencies, including any expert engaged by either of them, shall be permitted:

12.1 Upon reasonable notice, access during normal business hours to all nonprivileged books, ledgers, accounts, correspondence, memoranda, reports, accountant's work papers and other records, and documents, in the possession or under the control of Mission Health or its independent auditors, relating to any matters contained in the COPA, the First Amended COPA or this Second Amended COPA;

12.2 Upon reasonable notice, access during normal business hours to interview directors, officers, managers, or employees regarding any matters contained in the COPA, the First Amended COPA or this Second Amended COPA; and

12.3 Upon reasonable notice, to call a special meeting of the Board of Directors of Mission Health.

12.4 The State Agencies will endeavor to provide notice to Mission Health of any concerns raised by the Periodic Report, the Interim Report, or any other information tending to show that Mission Health may not be in compliance with any of the conditions of the COPA, the First Amended COPA or the Second Amended COPA, within a reasonable time after its receipt. Mission Health, and its board of directors, shall meet with the Department of Health and Human Services and/or the Attorney General, upon request, to attempt to resolve any such concerns.

(13) Board of Directors.

13.1 An important element of assuring that the granting of this Second Amended COPA will be in the public interest is that the Boards of Directors of Mission Health, Inc. and Mission Hospitals, Inc. will be composed primarily of members of the community who have an interest in low-cost medical care and who have no ties to either entity. Accordingly, the Boards of Directors of Mission Health, Inc.

and Mission Hospitals, Inc. which may be composed of the same members, shall be composed as follows:

> The Boards of Directors shall consist of twelve (12) to nineteen (19) persons selected through the consideration of appropriate competency-based criteria to (1) regard and protect the interests of recipients and purchasers of hospital-based health care services, and (2) help assure that Mission Hospitals provides cost-effective, efficient, and high-quality health services. The selection process should include a specific effort to assure that the interests of large and small employers; racial and ethnic minorities; women and men; and economically disadvantaged citizens are represented on the Boards. The Boards may also include physicians having medical staff membership and other persons having clinical practice privileges at Mission Health's facilities.
>
> At least one member of the Board shall be affiliated with a private employer that employs more than 200 employees in the service area and at least one member shall be affiliated with a private employer that employs more than 300 employees in the service area.

13.2 Mission Hospitals' Chief Executive Officer may serve as an *ex-officio* member of its Board of Directors, with vote; Mission Health's Chief Executive Officer shall be an *ex-officio* member of its Board of Directors, with vote; the Immediate Past Chair of each entity may serve as an ex-officio member with vote, and the Chairman of Mission Healthcare Foundation, Inc. shall be an *ex-officio* member with vote, but these *ex-officio* members are in addition to the twelve-to-nineteen-member figure referred to in ¶ 13.1 above.

13.3 All Board members of Mission Health other than the *ex-officio* members shall serve on the same conditions, shall be removed only for cause upon the affirmative vote of a majority of the remaining members of the Board, and shall

be limited to serving three consecutive terms of three years (or nine consecutive years) including time previously served on the Memorial Mission Medical Center board or the Mission-St. Joseph's Health System board.. Members of the Board of Mission Hospitals shall be appointed by the Board of Mission Health and may be removed at any time by the Mission Health Board with or without cause.

13.4 Membership on the current Boards consists of 18 persons including four physicians on the medical staff. This number does not include the ex officio members. This kind of representation appears to provide medical and administrative expertise while preserving public interest through a membership of broad based community representatives, who have no ties to Mission Health, and whose primary interest would seem to be low-cost, high-quality medical care. If and when the overall mix, composition, or size of the membership of the Boards is to be changed, Mission Health shall submit the proposed changes in advance to the State Agencies, and shall implement the changes only if the State Agencies do not object within thirty days. Any future reduction in the number of Board members shall begin with one of the positions reserved for physicians.

The above requirement is established because of the economic nature of a Certificate of Public Advantage. In terms of an economic relationship, the patients and consumers of health services at Mission Health have interests that can be in conflict with the economic interests of physicians, other clinicians and administrators.

(14) Change of Legal Status or Sale.

14.1 Mission Health and its constituent hospitals shall retain their status as non-profit entities. Any sale or transfer of control of Mission Health, or either of its constituent hospitals, shall take place only with the prior written approval of the State Agencies. Such approval may be upon conditions.

14.2 The State Agencies' approval shall not be required in the case of the sale or transfer of control to another not-for-profit entity or organization which has a

mission and vision for the delivery of cost-effective and quality health care services consistent with that of Mission Health, and the acquiring entity provides the State Agencies its agreement in writing that it is subject to this Second Amended COPA.

(15) Legal Exposure. No provision of this Second Amended COPA shall be interpreted or construed to require Mission Health to take any action, or to prohibit Mission Health from taking any action, if that requirement or prohibition would expose Mission Health to significant risk of liability for any type of negligence (including negligent credentialing or negligence in making referrals) or malpractice.

(16) Averment of Truth. By consenting to and signing this Second Amended COPA, Mission Health and Mission Hospitals aver that the information they have provided to the State Agencies in connection with first the COPA, the First Amended COPA and the Second Amended COPA to the best of their knowledge, is true and represents the most recent and comprehensive data available, and that no material information has been withheld.

(17) Review and Amendment. The State Agencies, Mission Health and Mission Hospitals agree to review this Second Amended COPA at least every two years and to consider appropriate amendments by the written agreement of the parties.

(18) Binding Effect of COPA. The terms of this Second Amended COPA are binding on Mission Health, Mission Hospitals, their successors and assigns, directors and officers, and all persons and entities in active concert or participation with any of them.

(19) Effective Date of Second Amended COPA. This Second Amended COPA shall become effective upon the consent of Mission Health and Mission Hospitals to the terms and conditions contained herein, as reflected by depositing in the U.S. Mail, by, a copy signed by the respective officers shown below, with first class postage affixed thereto, and addressed to the Department. Section (4) of the Terms and Conditions of this Agreement shall be applied in determining compliance with the cost and operating margin limitations for 2004 and subsequent years.

This document may be executed in multiple counterparts.

This the 30th day of June, 2005.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Robert J. Fitzgerald
Director
Division of Facility Services

Agreed and Consented to:

MISSION HOSPITALS, INC.

Joseph F. Damore, President

Date: 6/22/05

MISSION HEALTH, INC.

Joseph F. Damore, President

Date: 6/22/05

EXHIBIT

M

Sent: Tuesday, April 12, 2011 8:59 AM
Subject: message on behalf of Ron Paulus

As you know, a complex set of dynamics impacting the delivery of healthcare services has existed in our region for some time. Close to home, those dynamics include those related to the joint development of the Mission-Pardee ambulatory health campus on the County line in Fletcher. This morning Pardee's medical staff was informed that "the Henderson County Board of Commissioners has initiated discussions with University of North Carolina Healthcare System (UNC-Chapel Hill)...to explore a possible relationship." Press releases from Pardee and UNC Health Care will be forthcoming later this morning, but I wanted you to know as soon as the Pardee medical staff knew. Once the press release is available, I will share that with you.

As you also know, Mission has well established, collaborative relationships with both UNC and Pardee. Each has kept us aware (subject to confidentiality agreements) of the evolution of certain elements of the UNC-Pardee discussion. As stated in the release, the nature of any relationship that might actually develop between UNC and Pardee is yet to be defined. Similarly, how the UNC-Pardee discussions or possible relationship might impact our own relationships with UNC and/or Pardee is also yet to be defined.

What is clear at this time is that Mission and Pardee will continue to move forward developing the Fletcher health campus, an innovative project that will increase access to needed services in one of the fastest growing areas in Henderson and Buncombe Counties. UNC has been briefed on the project and indicated to us that it supports the ongoing project with Mission. We look forward to continuing dialogue in this regard.

Of course, we will carefully monitor and assess the progress of these discussions and our relationships to determine what course of action is in the best interest of our region's patients, physicians and Mission Health System.

As the situation develops, we will keep you informed to the fullest extent possible.

Best Regards,

Ron

Ronald A. Paulus, MD
President and CEO
Mission Health System
509 Biltmore Avenue

Asheville, NC 28801
Ron.Paulus@msj.org
www.msj.org

Assistant: Velinda Fisher
Velinda.Fisher@msj.org
Tel: 828-213-1144
Fax: 828-213-0196