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Carolina Mountain Gastroenterology Endoscopy Center, LLC Comments in Opposition to the CON Application Filed by Mission Hospital, Inc. to Relocate One GI Endoscopy Room to Fletcher, North Carolina Project I.D. No. B-008638-11

Carolina Mountain Gastroenterology Endoscopy Center, LLC ("Carolina Mountain Gastroenterology") hereby submits these comments in opposition to the CON Application submitted by Mission Hospital, Inc. ("Mission") on March 15, 2011 ("Mission GI South"), proposing to relocate one GI endoscopy room from the Mission Hospital Asheville campus to Hendersonville Road on the border of Henderson and Buncombe Counties. The Mission Application was denominated Project I.D. No. B-008638-11.

Although the Mission GI South application is a relocation project, it must conform to <u>all</u> the statutory review criteria and applicable standards of the CON Law. Fundamentally, the CON Section should deny the proposed Mission GI South application because there is no need for the proposed project. In addition to its non-conformity with Criterion 3, the Mission GI South application is also non-conforming to multiple other CON review criteria, any one of which is sufficient to warrant denial of the application. *Presbyterian Orthopaedic Hospital v. NCDHR*, 122 N.C. App. 529, 534, 470 S.E.2d 831, 834 (1996).

I. Carolina Mountain Gastroenterology

Carolina Mountain Gastroenterology is a physician-owned practice and outpatient endoscopy center located on Fleming Street in Hendersonville, approximately 11 miles from the proposed Mission GI South facility. Carolina Mountain Gastroenterology, started by Executive Manager Dr. Carl P. Stamm, has been serving Henderson, Buncombe and Transylvania Counties for the past 19 years. Carolina Mountain Gastroenterology has four physicians and four physician extender providers serving two office locations.

Carolina Mountain Gastroenterology has two grandfathered endoscopy rooms at its Hendersonville location. The physicians at Carolina Mountain Gastroenterology are and have been committed to providing the highest quality services for their patient population in a state-of-the-art setting.

Carolina Mountain Gastroenterology consistently provides a demonstrated high quality level of service to patients, including providing state-of-the-art technology in an equally high-tech facility. Carolina Mountain Gastroenterology regularly conducts patient satisfaction surveys and 98% of its patients report high levels of satisfaction with their experience at Carolina Mountain Gastroenterology. Ground level parking is always adequately available to patients who report the highest level of satisfaction with the physical accessibility of the endoscopy center.

Carolina Mountain Gastroenterology has also made a significant investment in the community because it employs 47 individuals, including anesthesiology, medical and administrative support staff. Maintaining these jobs for workers in this lean economy is especially important to the overall welfare of the Hendersonville and Buncombe County area.

The Agency should consider these facts as it reviews the Mission application. This project is nothing more than a market share "grab" by a provider that already has a monopoly on acute care hospital services in Buncombe County and has an increasingly dominant presence in Henderson County. For more details on this point, please refer to the report of Gregory S. Vistnes, Ph.D., attached as Exhibit B.

II. Mission GI South Application

Mission currently operates six licensed endoscopy rooms at its Asheville hospital campus. As evidenced by the Mission GI South application itself on page 31, Mission's outpatient endoscopy case and procedure volumes have been declining since 2008. Although there is a noticeable discrepancy between the data reported on its annual Hospital License Renewal Application ("LRA") and Mission's own internal data, this decline in volume is still strikingly evident no matter how the data is viewed. *See* Mission GI South Application, p. 45.

In the proposed project, Mission seeks to relocate one of those underutilized endoscopy rooms to a leased medical office building ("MOB") space in Fletcher, North Carolina. However, at least a portion of the leased MOB space appears to be located in Henderson County, North Carolina as shown in the architectural line drawing in Exhibit 29 of the Mission GI South application.[1] Although the address is reported to be in Buncombe County, the drawings and deeds included in the application indicate that at least part of the MOB, and part of the proposed endoscopy room itself, actually lie in Henderson County. For all practical purposes, the State should consider this to be more of Henderson County project than a Buncombe County project. Therefore, the State should be concerned about increasing the inventory of endoscopy rooms in Henderson County. Despite the fact that there is no county-specific need methodology for endoscopy rooms like there is for operating rooms, Mission must still demonstrate there is a need for this endoscopy room on Hendersonville Road. The concern over the endoscopy room's location is amplified given that there is excess capacity in Henderson County now, as addressed in greater detail below. Regardless, this project clearly impacts not only Buncombe County, but also to a substantial extent, Henderson County.

[1] *See also* Mission GI South Application Exhibit 28, property deeds for the proposed facility describing the property as being located in Buncombe and Henderson Counties and being recorded in both counties.

III. Mission GI South is Non-Conforming with Criterion 3.

A. Mission's endoscopy utilization rates are decreasing.

Need is the cornerstone of the CON review process. It is the applicant's burden of proof to demonstrate that the population it proposes to serve is actually in need of the service at the proposed location. *See* N.C. Gen. Stat. § 131E-183(a)(3). Although there are no specific need determinations for endoscopy rooms, an applicant such as Mission, who proposes to relocate an existing resource, must demonstrate that the relocated room is needed in its proposed new location. In other words, just because the endoscopy room is in existence in one area does not necessarily mean that it is needed to serve a different population in another location. *See* Agency Findings dated April 6, 2011, Wake Forest Ambulatory Ventures, LLC, Project I.D. No. G-8608-10, denying a proposal to relocate existing licensed operating rooms from Winston-Salem to Clemmons, Forsyth County.

The Mission GI South project is not needed. As demonstrated clearly in the Mission GI South application, endoscopy use rates in Buncombe County are decreasing. *See* Application, p. 34 and Exhibit 16, Table 9. Mission proposes to garner 56.8% of its patient base from Buncombe County. Moreover, Mission's own outpatient endoscopy volumes are also decreasing. Page 31 of the application shows that between 2008 and 2010, cases have decreased by 267 and procedures decreased by 194. Utilizing the 1,500 procedures per room performance standard in the endoscopy rules as a benchmark for performance, Mission's total outpatient volume shows a need for only 5.77 rooms. Thus, Mission barely has sufficient volume to justify its current complement of six endoscopy rooms.

Furthermore, although Mission relies upon the growth in endoscopy procedures at The Endoscopy Center in Buncombe County to justify its projections that Buncombe County needs 4.6 additional endoscopy rooms, Mission's own endoscopy utilization is declining. It is critical that the State hold Mission to task on this point as Mission is the applicant and cannot bootstrap an appearance of need by relying upon another facility's growth. Moreover, there is clearly significant capacity available at Mission to address any purported additional need for endoscopy rooms in the Asheville area.

It would be consistent with past Agency decisions to deny the Mission application based on this deficiency alone. In 2010, the Agency denied an application by Wake Radiology, Project I.D. No. J-8534-10, to acquire an MRI in Wake County due to Wake Radiology's declining volumes at an existing facility. Similarly, the aforementioned Wake Forest Ambulatory Ventures Findings denied a proposal to relocate operating rooms where the applicant failed to explain a decrease in current inpatient operating room volumes. The basis for this approach by the State is well-reasoned: if an applicant is experiencing decreases in existing services, how can the Agency rely upon representations that in the future the utilization will increase? Historical experience is worth a thousand words.

B. <u>The Mission GI South methodology relies upon unsupported assumptions</u>.

Although it is proposing to move an endoscopy room to a location closer to Henderson County than the current Mission campus, Mission proposes to have the exact same patient origin percentages that it currently experiences in the Asheville location. This is both unexplained, and unreasonable. Clearly by placing this endoscopy room right on the county line (and actually over the line, according to the drawings and the deeds contained in the application), Mission is seeking to grow its Henderson County patient base and take patients away from existing providers including Carolina Mountain Gastroenterology. There is no other reason for this project, as the volumes do not justify the relocation, nor are there any special circumstances present, such as a lack of convenient access to outpatient endoscopy.

The Mission GI South application assumes that population growth, particularly among the age 65 and older cohort, will necessarily lead to increased utilization of its endoscopy rooms in the future. Mission also assumes that future economic improvements including economic development in the proposed service area will lead to increases in endoscopy utilization. These assumptions are just that—suppositions for which no supporting documentation is provided. Mission also fails to document a link between these speculative growths and endoscopy utilization.

In its utilization methodology, Mission actually acknowledges its declining volumes as it develops its "growth" rate of <u>negative</u> 0.2%, found on page 48 of the application. Consistent with a negative growth rate, Mission projects to perform fewer endoscopy procedures and cases by Project Year 3, 2015, than it did just last year in 2010. *See* Application p. 49. If there was any doubt that the proposed project was not needed, this negative growth rate and projected future decrease in volume clearly resolves that issue. This also undermines Mission's assumptions that future growth in the aging population and future economic growth will turn things around for its outpatient endoscopy volumes.

Again, just because an applicant has an existing service it does not mean that service is necessarily needed in another location for a different population, and this is a case in point. Mission attempts to soften the blow of its projected decreasing volumes by stating the decrease is "very slight." This is not the point. The volumes are still continuing to decrease by Mission's own projections and calculations. Mission also tries to bolster its position by stating it has a need for 6 endoscopy rooms. However, the "need" that Mission is required to prove in this application is that there is a "need" for a relocated endoscopy room to serve the new proposed 9 zip code service area. Whether or not Mission needs the 6 rooms at its Asheville campus (which is itself a questionable proposition), is not before the Agency in this review. It is unreasonable for Mission to expect the CON Section to reward its decreasing utilization trend and authorize the expenditure of more than $1.2 million to relocate a service to an area that already operates with an excess capacity of endoscopy rooms.

Mission also attempts to rely upon population growth in the proposed service area in Steps 6 through 8 of its methodology. However, it does not matter how much the population grows if the procedure volume growth is <u>negative</u>. Mission's market share for endoscopy procedures in both Buncombe and Henderson Counties has also experienced a decrease while Carolina

Mountain Gastroenterology, for example, experienced a substantial increase of 31.2 basis points in its market share. *See* Application p. 56.[2]

Despite the historical and projected decreases in utilization, negative growth rate, decreased volumes, and decreases in market share, Mission still maintains that Mission GI South will "reasonably" capture 70% of the Mission campus endoscopy volume. Thus, Mission GI South projects to capture 22.7% of the Buncombe County endoscopy market and 5.1% of the Henderson service area market. This is far from reasonable, is counterintuitive and not explained by the applicant.

Mission GI South's projections, albeit unreasonable, still fall below the planning threshold in the endoscopy rules which requires a demonstration that an applicant will reach 1,500 procedures per room per year. Mission GI South falls short of this threshold and projects to provide only 1,487 procedures by project year 3, even with the inclusion of an unsubstantiated 10% "inmigration."

On page 58 of the application, Mission GI South projects that an additional 149 procedures (10%) in Project Year 3 are attributable to what it calls "inmigration." Mission's application, however, is void of any discussion validating the 10% assumption or even explaining the basis for the 10%. Additionally, Exhibit 15, Table 5 of the application represents inmigration to be 15%. This discrepancy is not explained and thus Mission's inmigration assumptions are unreliable.

The inmigration assumption is also unreliable because Mission fails to identify where those purported patients would come from with any specificity. As discussed above, it is also unreasonable to project that residents in "other" zip codes, potentially located great distances from Mission GI South in counties other than Buncombe and Henderson, would bypass existing facilities to reach the proposed new location in Fletcher. Again, because no detail is provided by the applicant, the Agency cannot reasonably rely upon the application's vague representations that this inmigration will actually occur.

C. Mission fails to demonstrate a reason why the proposed relocation is necessary or benefits the purported service population.

Mission makes several unsubstantiated claims with respect to why it is proposing to relocate an endoscopy room to the Henderson/Buncombe Counties' border.

Mission argues that there is insufficient geographic access to existing endoscopy resources in the Asheville area. There is no merit to this argument. Mission fails to present any evidence that patients have experienced, let alone expressed, an inability to physically access available endoscopy services in the service area. Asheville, contrary to the representation made by Mission, is an easily-accessible city. Although Mission attempts to downplay its Asheville campus and facilities, there is no indication that patients have expressed any concerns with

[2] Despite the increase in market share, the number of procedures performed at Carolina Mountain Gastroenterology declined from FFY 2008 to FFY 2009. *See* discussion on page 7 of these comments.

respect to traffic or parking. Mission has in fact made efforts to ensure its campus is easily accessible, including providing shuttle services, free parking to visitors and patients, and valet parking for a modest charge.

Even if there was some dissatisfaction with the accessibility of the Mission campus, there are multiple other outpatient endoscopy facilities that provide surface parking and additional access to the proposed service area. In fact, utilization at one of those facilities, The Endoscopy Center, less than one mile from Mission, has reported high procedure volumes. Clearly there are accessible options for patients in the Asheville area, even if they are not choosing the Mission campus. There is no evidence provided to correlate patient choice with impaired geographic access.

Mission's nine zip code service area would actually make geographic access for some of its proposed patients more difficult. This is because Mission assumes that patients from zip codes 28791 and 28972 will bypass existing providers with a combined total of 6 endoscopy rooms, including Carolina Mountain Gastroenterology, Pardee Hospital, and Park Ridge Hospital, in order to seek endoscopy services in a one room facility located in an MOB. This bizarre proposition does not make good health planning sense, and the applicant makes no effort to explain why patients would drive past existing facilities.

D. The proposed project suffers from a lack of patient and physician support.

Mission does not provide any letters from physicians committing to perform any quantified numbers of procedures at the proposed Fletcher location. Although four physicians from The Endoscopy Center, an aggressive competitor of the Mission Asheville campus endoscopy rooms, signed a letter of interest, none commits to utilizing the proposed facility. It is doubtful, absent some agreement between Mission and The Endoscopy Center which is not addressed in the application, that a competitor would actually support a project with the potential to take revenues out of its own pocket.

It is also noteworthy that there are no letters of support from patients for the proposed project, despite the purported desirable location of the Mission GI South endoscopy room. As previously noted, the application also lacks evidence that patients do not currently enjoy sufficient access to endoscopy services in Buncombe and Henderson Counties.

Thus, the application is non-conforming with Criterion 3 and should be denied.

IV. Impact on Carolina Mountain Gastroenterology

As explained in great detail above, the Mission GI South project is non-conforming with Criterion 3 because it fails to demonstrate a need that its proposed population, Buncombe and Henderson County residents, has for this endoscopy room at its proposed new location. Because the relocation is not needed, if the proposed Mission GI South project is approved, it will have an enormous negative impact on endoscopy services for the patients of Henderson

and Buncombe Counties as the viability of the Carolina Mountain Gastroenterology practice will be threatened.

As previously noted, endoscopy use rates at both Mission Hospital and in Buncombe County have been rapidly decreasing. The Mission GI South application itself shows a decline from 51.8 in FY 2007 to 49.1 in FY 2010. *See* Application, p. 34 and Exhibit 16, Table 9. Although Henderson County's use rate has increased slightly (from 55.7 to 58.2) during that same time period, the combined use rate was still well below four years ago in 2007.

Consistent with the information provided in the Mission GI South application and the indisputable evidence of declining endoscopy utilization, the providers at Carolina Mountain Gastroenterology have felt first-hand the decrease in endoscopy utilization in the proposed service area over the last few years. Despite being an established practice with long-standing referral relationships and patterns in the community, Carolina Mountain Gastroenterology's own case and procedure volumes combined declined sharply between 2008 and 2009:

	Cases	Procedures
10/1/2007 - 9/30/2008	3,541	3,646
10/1/2008 - 9/30/2009	2,551	3,316[3]

As a result of declining volumes, Carolina Mountain Gastroenterology has actually decreased the number of days its providers perform procedures in its endoscopy center. This result is pure cause and effect necessitated by declining volumes in the same community to which Mission GI South now proposes to add capacity. Carolina Mountain Gastroenterology's best estimate of its current excess capacity is thirty to forty percent. Thus, Carolina Mountain Gastroenterology has the capacity to increase its volumes by **30% to 40%** above current volumes in its existing, state-of-the-art endoscopy center without investing one more cent to make such an accommodation. An increase of only 30% above reported 2008 procedures is nearly 67% the total volume Mission GI South projects to attain by 2015. This is to say nothing of the excess capacity at other local endoscopy centers in the proposed service area such as Park Ridge Hospital or Margaret R. Pardee Memorial Hospital in Henderson County, which have also been faced with decreasing volumes and therefore excess capacity in recent years.

Adding yet another outpatient endoscopy room to the pool of existing rooms in a population utilizing endoscopy less and less will only exacerbate the problem already facing this service area. Because there is no need and no demand for additional capacity to serve this area, an additional endoscopy room will only mean there are fewer cases and procedures to go around and existing rooms will continue to be underutilized, in direct contravention of the CON Law. *See, e.g.,* N.C. Gen. Stat. §§ 131E-175(3), (4) and (6) and 131E-183(a)(3) and (a)(6). This is because Mission GI South would necessarily be taking patients away from other providers,

[3] Source: Table 6E 2010 SMFP; Table 6E 2011 SMFP.

namely the physician-owned Carolina Mountain Gastroenterology practice. This is a waste of healthcare resources that will only increase the costs of these services to patients and payors. The only party standing to benefit from this opportunistic project is Mission.

The approval of the Mission GI South project also has the real potential to result in the loss of a substantial percentage of Carolina Mountain Gastroenterology's patient base. Currently, more than 25% of Carolina Mountain Gastroenterology's patients originate from Buncombe and Transylvania Counties. The remaining approximately 75% are Henderson County residents. As explained above, because there already exists a great deal of excess capacity of endoscopy rooms in the proposed service area, and because there is no need for the Mission GI South project, that proposed facility would not be needed to serve new patients, but would essentially be stealing patients away from established existing providers. Carolina Mountain Gastroenterology is at a real risk of losing that 25% of its patient base if the Mission GI South project is proposed. Mission controls all the non-federal acute care hospitals in Buncombe and Transylvania Counties, and has a substantial hold on referral sources from these two counties.[4] Mission's market power could easily cause the diversion of patients previously referred to Carolina Mountain Gastroenterology, to its proposed Mission GI South. Carolina Mountain Gastroenterology could not recover from such a significant loss.

If faced with an even greater excess capacity in its existing endoscopy center, Carolina Mountain Gastroenterology could legitimately face an unsustainable loss that may force it to shut its doors. Carolina Mountain Gastroenterology is the second largest provider of endoscopy procedures in Henderson County second to Pardee Hospital. Forty-seven jobs would be at risk and a high quality, state-of-the-art facility will be wasted. With two fewer endoscopy rooms in the area, patient access would surely be decreased. Such a result is clearly the polar opposite of the legislature's intention in enacting the State's CON Law. *See* N.C. Gen. Stat. § 131E-175.

V. Mission GI South is Non-Conforming with Criterion 3a.

Criterion 3a requires that applicants "demonstrate that the needs of the population presently served will be met adequately by the proposed relocation. . . . 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." N.C. Gen. Stat. § 131E-183(a)(3a). Criterion 3a does not apply in all circumstances, but the legislature has specifically mandated proposals to relocate services, such as the Mission application, address this important requirement. That is because the relocation of an existing service not only impacts the proposed new service area, but it also impacts the existing service area where access will be reduced by removal of the service.

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[4] Effective January 1, 2011, Mission became the manager of Transylvania Regional Hospital (TRH) in Brevard. TRH is the only hospital in Transylvania County. *See* http://www.blueridgenow.com/article/20101228/articles/12281016. It is worth noting that according to Table 6E of the 2011 SMFP, TRH's two endoscopy rooms are also underperforming.

Mission fails to address how its proposed relocation will affect patients it currently serves from Madison and Yancey Counties. *See* Application p. 71, chart depicting Mission Hospital endoscopy service area. Mission GI South is proposed to be located on the Buncombe/Henderson County border. That means Yancey County and Madison County patients would be required to travel through Buncombe County, bypassing other endoscopy providers, including the Mission Hospital Asheville campus, in order to reach the new proposed facility. This is not likely to occur, and therefore those patients currently served by Mission in Asheville will have one less endoscopy room to meet their needs.

This reduction in access should be of particular concern to the Agency when it considers the resources and population of Madison and Yancey Counties. Madison and Yancey Counties are predominantly rural counties. There are no hospitals or ambulatory surgical facilities located in Madison and Yancey Counties. Of the approximately 40,000 residents in Madison and Yancey Counties, 19.3% and 17.8% live below the poverty line, respectively. Thus, this patient population already has strained access to healthcare services and facilities. Many of these residents do not have the means to spend even more money to receive health care services. For example, with gas rates approaching $4.00 per gallon, it is unlikely and unfair to expect patients to travel further for healthcare services such as endoscopy.

The non-conformity with Mission's application is that it fails to even consider this impact or address how it proposes to continue meeting the needs of Madison and Yancey residents by moving one endoscopy room further away. Instead of ensuring it will meet the needs of its current patient population, the Mission GI South proposal would relocate a service closer to a population whose needs are being met in an area already saturated with endoscopy rooms.

Thus, the application is non-conforming with Criterion 3a and should be denied. *See also* N.C. Gen. Stat. § 131E-175(3a)("That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.").

VI. <u>Mission GI South is Non-Conforming with Criterion 4.</u>

Criterion 4 requires the applicant to demonstrate that it has selected the least costly or most effective alternative. *See* N.C. Gen. Stat. § 131E-183(a)(4). The Mission GI South project is <u>not</u> the least costly or most effective alternative because the applicant has failed to demonstrate need for the project, as discussed at length with respect to Criterion 3. The least costly and most effective alternative for Mission is to maintain the status quo of its services and invest its time and efforts in filling the excess capacity at its existing Asheville campus, not to spend more than $1.2 million to relocate to an area already saturated with outpatient endoscopy rooms. The approval of Mission GI South would also exacerbate the underutilization of existing endoscopy rooms in Buncombe and Henderson Counties leading to increased healthcare costs and waste of existing, high quality providers.

Thus, the application is non-conforming with Criterion 4 and should be denied.

VII. Mission GI South is Non-Conforming with Criterion 5.

Criterion 5 requires applicants to demonstrate both the financial feasibility of their project and the availability of funds for their proposed project. *See* N.C. Gen. Stat. § 131E-183(a)(5). Although the Mission GI South project is not financially feasible, as detailed below, even if it were assumed to be financially feasible for the sake of argument, Mission fails to demonstrate available funds for this project, and is therefore non-conforming with Criterion 5.

Question VIII.6. of the application requires the applicant to: "Submit documentation of the availability of accumulated reserves, such as a letter from the appropriate official who is fiscally responsible for the funds." Mission's response is to: "Please see Exhibit 26 for a letter from Charles F. Ayscue, CFO of Mission Hospital, verifying that funds from operations or cash reserves are available to fund the project. Please also see Exhibit 27 for a copy of Mission Hospital Inc.'s fiscal year 2009 and 2010 audited financial statements."

In Exhibit 26, Mission includes a letter from its CFO dated March 15, 2010, "Re: Mission Hospital, Inc. CON Application for the Addition of Nine General Acute Care Beds April 1, 2010 Review Period." The letter purports to commit $245,000 for the referenced project. The current project submitted in 2011, is not for acute care beds. Moreover, the total purported cost of this project is substantially greater: $1,237,236. This outdated letter does not commit funds for the proposed project. There are no other letters committing funds for the endoscopy project and such a demonstrated commitment cannot be waived or assumed to exist by the Agency. This is indisputable, as recently found by Administrative Law Judge Don Overby in the Onslow MRI appeal in 2010. There, an applicant, Onslow MRI, LLC, failed to include all costs associated with it project and failed to submit a clear commitment of funds for the total amount of the project due to said omission. Judge Overby recommended upholding the Agency's determination that Onslow MRI was non-conforming with Criterion 5. *See* Recommended Decision, *Onslow MRI, LLC v. N.C. Dept. of Health and Human Services, etc. and Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging*, File No. 09 DHR 5617 and *Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging v. N.C. Dept. of Health and Human Services, etc. and Onslow MRI, LLC*, File No. 09 DHR 5638, attached hereto as Exhibit A. The same result should apply here.

The Mission GI South also fails Criterion 5 because it is not financially feasible. Because Mission GI South has failed to demonstrate the need for its proposed relocation and relies upon unsubstantiated and undocumented assumptions to arrive at its projections, its financial projections cannot be relied upon by the Agency. The basis for Mission's cost and revenue projections are its utilization projections. When an applicant's utilization projections are unreasonable, as discussed with respect to Criterion 3 above, cost and revenue projections resulting therefrom are also unreliable.

Mission GI South's capital cost projections are understated. *See* Application p. 110. Mission GI South provides no basis or assumptions for its average charge per case. Although the land deeds included in Exhibit 28 of the application show that Mission owns the land upon which the MOB housing the endoscopy room sits, which it will then lease to the MOB developer, it fails to allocate the land acquisition cost to the Mission GI South project. *See* Application pp. 99, 111. There are also no start-up or initial operating expenses included in Mission GI South's proposed project for this brand new facility. In fact, section IX. of the application is left entirely blank and unanswered. Furthermore, in Section VII. of the application, Mission fails to account for all necessary clinical and administrative personnel, which calls into question the accuracy and reliability of those respective salaries and benefits reported in the pro forma projections of the application. Mission has underestimated its costs and overestimated its projected revenues. Please see the discussion below regarding Criterion 7 for additional detail.

Question XI. 7(a) of the CON Application requires that applicants "Provide a certified estimate of the construction cost of the proposed project from an architect licensed to do business in North Carolina." Mission did not provide a "certified cost estimate," but instead provided a "conceptual cost estimate." *See* Application Exhibit 29. There is no evidence in the application that a preliminary "conceptual" cost estimate is an adequate substitution for the required "certified cost estimate."

In addition to its failure to include land costs, there is no inclusion of space in the facility plans for endoscopy patient registration, reception, or waiting room space. There are also two unexplained deductions: $92,500 for "landlord tenant improvement allowance," and $510,232 for a "60% ownership adjustment." Based upon the information provided in its application, no landlord legal entity is yet in existence to support the nearly $100,000 adjustment. *See* Exhibit 34 to the application. There is no explanation provided to justify these deductions.

The "conceptual" cost estimate also assumes a 4.28% pro rata share of the projected site, shell and core costs of the MOB. However, again, this calculation goes unexplained and unsubstantiated by the applicant. For all of these reasons, the architect's "conceptual" capital cost estimate is unreliable. The Mission application has therefore failed to set forth a financially feasible project and fails to demonstrate the availability of funds.

Thus, the application is non-conforming with Criterion 5 and should be denied.

VIII. Mission GI South is Non-Conforming with Criterion 6.

The Mission GI South project is non-conforming with Criterion 6. Criterion 6 requires Mission to demonstrate that its proposal will not result in the unnecessary duplication of existing services. *See* N.C. Gen. Stat. § 131-183(a)(6). The Mission GI South project is all about the unnecessary duplication of existing services.

As discussed at length above, there is already excess endoscopy capacity in Henderson and Buncombe Counties. Because those existing providers, such as Carolina Mountain Gastroenterology, have excess capacity to be filled for a service experiencing decreases in utilization, the relocation of one of Mission's endoscopy rooms to the Buncombe/Henderson line will only add to the excess capacity and duplicate those available rooms already providing services in the service area.

It is worth noting that Mission itself cannot explain why the existing endoscopy rooms in the service area cannot adequately meet its purported need to relocate one endoscopy room to Fletcher. The CON Section specifically asks the applicant to provide specific documentation on this point and Mission's response that the relocation will provide "better geographic access to services by Mission" is not an answer to the question. *See* Application, p. 73.

Moreover, the project is not needed and the application is non-conforming with Criterion 3. As such, an unneeded project necessarily duplicates existing resources, such as those available at Carolina Mountain Gastroenterology.

Thus, the application is non-conforming with Criterion 6 and should be denied.

IX. Mission GI South is Non-Conforming with Criterion 7.

Criterion 7 addresses the adequacy of the applicant's proposed staffing. *See* N.C. Gen. Stat. § 131E-183(a)(7). Although Mission GI South reports that it will provide anesthesia conscious sedation services and will have administrative staff such as receptionists and on-site registration and other business personnel, Section VII of the application's staffing projections fails to account for these necessary positions. *See* Application p. 9 and Section VII. Based on this failure, it is also reasonable to assume that Mission has failed to account for those respective salaries and benefits in its pro forma projections, thereby further underestimating its costs and overestimating its revenues. Please see the discussion under Criterion 5 above. As such, Mission has failed to demonstrate the availability of resources, "including health manpower and management personnel," and should be found non-conforming with Criterion 7.

Thus, the application is non-conforming with Criterion 7 and should be denied.

X. Mission GI South is Non-Conforming with Criterion 12.

Criterion 12 applies to applicants who are proposing construction, which is the case here. *See, e.g.*, N.C. Gen. Stat. § 131E-183(a)(12). The applicant is required to demonstrate that the cost, design and means of construction proposed represent the most reasonable alternative, and the construction project will not unduly increase the costs of providing health services. Mission GI South's application does not conform with the requirements of Criterion 12. Exhibit 29 of the Application contains a site plan attached to the "conceptual" cost estimate from the architect. However, the plan is not adequately labeled and there is no way to even

tell where the endoscopy room itself will be located. The same is true for the unlabeled and ambiguous line drawing in Exhibit 6. There is no detail in the application regarding other uses for the MOB, even though the "conceptual" cost estimate included deductions for the MOB. There is no way to judge the accuracy of the proposed plan or cost estimate.

Thus, the application is non-conforming with Criterion 12 and should be denied.

XI. Mission GI South is Non-Conforming with Criterion 18a.

Criterion 18a requires the applicant to demonstrate the expected effects of its proposal on competition. *See* N.C. Gen. Stat. § 131E-183(a)(18a). Because there is no need for the Mission GI South project, it will not have a positive impact on competition, as required under Criterion 18a. Mission claims in its application that it will promote cost effectiveness, quality, and access to care that will "equal or surpass" other local providers. *See* Application, p. 84. However, this statement is not consistent with the recent findings of economist Gregory S. Vistnes, Ph.D., who was hired by DHSR to analyze Mission's performance under its Certificate of Public Advantage ("COPA").

On March 1, 2011, the State of North Carolina published Dr. Vistnes' report entitled, *An Economic Analysis of the Certificate of Public Advantage (COPA) Agreement Between the State of North Carolina and Mission Health*, a copy of which is attached hereto as Exhibit B. In his report, Dr. Vistnes raised numerous problems with Mission's COPA, including the potential unfair competitive advantage it may give over other providers, and the incentive it creates for Mission to increase its outpatient prices. Mission is a state-regulated monopoly, and as such, its conduct must be actively supervised by the State of North Carolina. While the CON Section is not an antitrust regulatory agency, it, along with its colleagues at other DHSR sections, must exercise its regulatory powers to ensure that Mission does not exercise its considerable market power to the detriment of its few remaining competitors in Western North Carolina, most of whom are considerably smaller than Mission. This project, which exists for no other reason than to capture patients from other providers, is an excellent example of the problems Dr. Vistnes identifies in his report.

Beyond the antitrust issues raised by Dr. Vistnes' report, which will be assessed by the Medical Care Commission and the Attorney General's Office, these points are relevant to the CON review process. Mission's proposed relocation, as explained above, will likely result in Mission GI South pulling patients from existing providers in the Henderson and Buncombe County service area, such as Carolina Mountain Gastroenterology. Although Mission does not explicitly state that it will shift market share from existing providers, with its own volumes declining and utilization rates for endoscopy decreasing, there is no other place from which to pull patients. This will most certainly negatively impact existing providers like Carolina Mountain Gastroenterology which already provides high quality outpatient endoscopy services to this area. Allowing Mission to spend over $1.2 million on an unneeded service that will likely be underutilized and most certainly operate at the expense of existing providers, will only add to the excess capacity problems in the Buncombe and Henderson County service area.

This self-serving proposal is also an attempt by Mission to increase its market share in Henderson County, which has been steadily growing over the years. *See* Vistnes Report, Table 1. As noted above, the proposed facility appears to be located in both Henderson and Buncombe Counties. This choice of location was certainly no accident. The proximity to Henderson County presents an opportunity for Mission to increase its market share at the expense of existing providers like Carolina Mountain Gastroenterology. The application itself even makes note that its patient origin will not be "the same" as it is currently. *See* Application pp. 70-71.

For these reasons, the application fails to satisfy the requirements of Criterion 18a and should be denied.

XII. Mission GI South is Non-Conforming with N.C. Gen. Stat. § 131E-183(b).

If an applicant is non-conforming with any applicable rules promulgated by the Agency, it will be found non-conforming with § 131E-183(b) of the CON review criteria. Section II. 11. of the CON Application states: "For gastrointestinal endoscopy procedure rooms, review the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities." Mission takes the position that the endoscopy rules are not applicable to this review however, this position is not correct and Mission should be found non-conforming with § 183(b).

Mission claims the endoscopy procedure room rules do not apply to its proposed relocation because it "does not create a new GI Endoscopy Facility nor does it increase the number of GI Endoscopy rooms in Buncombe County." Neither of these purported reasons addresses the standards under which the rules are applicable. The term "GI Endoscopy Facility" is not defined in the CON Law. In addition, although the proposal may not increase the number of endoscopy rooms in Buncombe County, as detailed in the comments above in Sections III., IV. and V., it appears that at least part of the endoscopy room actually lies in Henderson County. This most certainly would change the inventory of endoscopy rooms in Henderson County.

"GI endoscopy room" is defined in 10A N.C.A.C. 14C.3901(2) as "a room as defined in G.S. 131E-176(7d) that is used to perform one or more GI endoscopy procedures." N.C. Gen. Stat. § 131E-176(7d) defines a gastrointestinal endoscopy room as "a room used for the performance of procedures that require the insertion of a flexible endoscope into a gastrointestinal orifice to visualize the gastrointestinal lining and adjacent organs for diagnostic or therapeutic purposes." Based on the information provided by Mission throughout its application, the proposed relocation will be of one endoscopy room where gastrointestinal endoscopy procedures will be performed.

The endoscopy room rules apply to an applicant proposing to establish a new licensed ambulatory surgical facility or to develop an endoscopy room in an existing licensed health service facility for performing endoscopy procedures. 10A N.C.A.C. 14C. 3902(a). An

ambulatory surgical facility is a facility to provide ambulatory surgical program, including a specialty program, where patients receive local, regional or general anesthesia and post-operative observation for fewer than 24 hours. N.C. Gen. Stat. § 131E-176(1b). Mission has proposed to utilize anesthesia for this outpatient (*i.e.*, less than 24 hour turnaround) endoscopy room. Therefore, it should have addressed the applicable endoscopy procedure room rules.

Mission cites to the Western Carolina Endoscopy Center Agency Findings in support of its position that the endoscopy rules are inapplicable to this project. That case is distinguishable, however, as Western Carolina was relocating an entire existing ambulatory surgical facility and thus not developing a new facility. Such is not the case with Mission whose existing rooms are licensed under the Hospital and not as a separate ambulatory surgical facility. Mission is proposing to create a new facility, albeit housed in a medical office building, for the provision of endoscopy procedures.

Mission notes that even though it was not required to answer the endoscopy procedure room rules, it did "take into consideration" the definitions and standards. However, Mission did not take these standards into consideration. This is evidenced most clearly by the fact that the volume projections for Mission GI South do not meet the planning threshold of 1,500 procedures per room articulated in 10A N.C.A.C. 14C.3903(b). The purpose of the planning threshold is to further ensure that a need for a proposed endoscopy room actually exists before it is approved by the Agency. In this case, Mission's own projected volumes are too low to meet this threshold. By project year three, Mission's projections, which are unreliable, inflated, and include unsubstantiated and undefined "inmigration," still fall below the 1,500 procedure standard. *See* Application, p. 58.

Even if the Agency determines that the endoscopy procedure room rules do not apply to this review, the 1,500 procedures per room planning metric is instructive for the CON Section's evaluation of whether or not the proposed project is needed. This proposed project is not needed and this could not be better evidenced than by the volume projections that fall below the State's planning guidelines.

XIII. Conclusion

For the reasons state above and included in the attached exhibits, the Mission GI South application fails to demonstrate need and is non-conforming to multiple statutory review criteria and rules and should be denied by the Agency.

STATE OF NORTH CAROLINA

COUNTY OF ONSLOW

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS

ONSLOW MRI, LLC,

Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent,

and

JACKSONVILLE DIAGNOSTIC IMAGING, LLC d/b/a COASTAL DIAGNOSTIC IMAGING,

Respondent-Intervenor,.

09 DHR 5617

Filed
2010 JUN 24 PM 1:47
Office of
Administrative Hearings

JACKSONVILLE DIAGNOSTIC IMAGING, LLC d/b/a COASTAL DIAGNOSTIC IMAGING,

Petitioner,

v.

N.C. DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE REGULATION, CERTIFICATE OF NEED SECTION,

Respondent,

and

ONSLOW MRI, LLC,

Respondent-Intervenor.

09 DHR 5638

RECOMMENDED DECISION

EXHIBIT
A

This matter came for hearing before the undersigned Administrative Law Judge ("ALJ"), on May 10-14, 19, 21, 25-28 and June 1-2, 2010, in Raleigh, North Carolina. The Court having heard all of the evidence in the case, considered the arguments of counsel, examined all exhibits, and relevant law, makes the following findings of fact, by a preponderance of the evidence, enters his conclusions of law thereon, and makes the following recommended decision.

APPEARANCES

For Petitioner/Respondent-Intervenor Onslow MRI, LLC ("OMLLC"):

S. Todd Hemphill
Matthew A. Fisher
Bode, Call & Stroupe, L.L.P.
Post Office Box 6338
Raleigh, NC 27628-6338

For Petitioner/Respondent-Intervenor Jacksonville Diagnostic Imaging, LLC d/b/a Coastal Diagnostic Imaging ("JDI"):

Denise M. Gunter
Candace S. Friel
Nelson Mullins Riley & Scarborough LLP
The Knollwood, Suite 530
380 Knollwood Avenue
Winston-Salem, NC 27103

For Respondent N.C. Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "CON Section" or "Agency"):

June S. Ferrell
Juanita B. Twyford
NC Department of Justice
Post Office Box 629
Raleigh, NC 27602-0629

APPLICABLE LAW

1. The procedural statutory law applicable to this contested case is the North Carolina Administrative Procedure Act (the "APA"), N.C. Gen. Stat. § 150B-1 *et seq.*

2. The substantive statutory law applicable to this contested case hearing is the North Carolina Certificate of Need Law, N.C. Gen. Stat. § 131E-175 *et seq.*

3. The administrative regulations applicable to this contested case hearing are the North Carolina Certificate of Need Program administrative rules, 10A N.C.A.C. 14C.2700, *et seq.*, and the Office of Administrative Hearings rules, 26 N.C.A.C. 3.0100 *et. seq.*

ISSUES

1. Whether the Agency exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in finding the CON application of OMLLC non-conforming with G.S. §§ 131E-183(a)(1), (3), (4), (5), (6), (7), (8), (18a), (18b), and with 10A N.C.A.C.14C.2703(b)(3)

2. Whether the Agency exceeded its authority or jurisdiction; acted erroneously; failed to use proper procedure; acted arbitrarily or capriciously; or failed to act as required by law or rule, in finding the CON application of JDI non-conforming with G.S. §§ 131E-183(a)(1), (3), (4), (5), (6), (13c), (18a), (18b), and with 10A N.C.A.C.14C. 2702(c)(8), .2702(c) (9) and 10A N.C.A.C.14C.2703(b)(3.

BURDEN OF PROOF

OMLLC bears the burden of proving by the greater weight of the evidence that the Agency substantially prejudiced their respective rights, and that the Agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule in finding OMLLC's application to develop a new diagnostic center and acquire one fixed MRI scanner in Onslow County, North Carolina non-conforming with statutory review G.S. §§ 131E-183(a)(1), (3), (4), (5), (6), (7), (8), (18a), (18b),

and with 10A N.C.A.C.14C.2703(b)(3); and JDI bears the burden of proving by the greater weight of the evidence that the Agency substantially prejudiced their respective rights, and that the Agency also acted outside its authority, acted erroneously, acted arbitrarily and capriciously, used improper procedure, or failed to act as required by law or rule in finding JDI's application to acquire one fixed MRI scanner for its existing diagnostic facility in Onslow County, North Carolina non-conforming with G.S. §§ 131E-183(a)(1), (3), (4), (5), (6), (13c), (18a), (18b), and with 10A N.C.A.C.14C. 2702(c)(8), .2702(c) (9) and 10A N.C.A.C.14C.2703(b)(3); and in disapproving both applications. G.S. § 150B-23(a); *Britthaven, Inc. v. N.C. Dept. of Human Resources, et al.*, 118 N.C. App. 379, 455 S.E.2d 455, 459, *disc. rev. denied*, 341 N.C. 418, 461 S.E.2d 754 (1995).

WITNESSES

Witnesses for Petitioner OMLLC:

Karin Lastowski Sandlin, Partner, Keystone Planning Group

David Brent Meyer, Senior Partner, Keystone Planning Group

Michael G. McLaughlin, M.D., President, Eastern Radiologists, Inc.

Bernetta Thorne-Williams, Project Analyst, CON Section

Walter Lindstrand, Chief Operating Officer, Eastern Radiologists, Inc.

William P. Franklin, Jr., Senior Vice President, First Citizen's Bank & Trust Company, Commercial Banking Department

Catherine J. Everett, M.D., Managing Partner, Coastal Radiology, PLLC

Elizabeth G. D'Angelo, M.D., Neuroradiologist, Coastal Radiology, PLLC

Daniel Carter, Managing Consultant, Health Planning Source

Witnesses for Petitioner JDI:

John Benedict Feole, M.D., President, Strategic Imaging Consultants

Kathryn M.T. Platt, President, Platt Health Care Management Consultants, Inc. **Witnesses for Respondent Agency:**

Helen Alexander, Team Leader, CON Section

EXHIBITS

Joint Exhibits

The following documents were Joint Exhibits admitted into evidence:

1. Agency File
2. JDI Application
3. OMLLC Application

OMLLC Exhibits

The following documents were offered by OMLLC and admitted into evidence:

101. SMFP: 2009 MRI Need Determinations and Methodologies
103. Chart: Onslow County Contrast Percentages
104. C.V. of David Meyer
105. Comments: New Hanover MRI Review 2005
106. C.V. of Catherine Everett, M.D.
107. American College of Radiology: Manual on Contrast Media, Version 6
108. Spreadsheet: Coastal Radiology Patient Origin Data
110. C.V. of Michael McLaughlin, M.D.
112. C.V. of Elizabeth D'Angelo, M.D.

119. C.V. of Bernetta Thorne-Williams

123. Transcript: Novant Health, Inc. and Medical Park Hospital, Inc. d/b/a Medical Park Hospital v. NCDHHS, 08 DHR 0688 and Davie County Emergency Health Corp. v. NCDHHS, 08 DHR 0689; Contested Case Hearing, Volume 11 (Excerpts) (p. 29)

125. C.V. of Helen Alexander

135. Agency Findings: NCBH Outpatient Diagnostic Imaging Center Review

136. Agency Findings: New Hanover MRI Review

137. Agency Findings: Presbyterian Hospital – Mint Hill Review

142. Agency Findings: Carteret County General Hospital Corporation d/b/a Carteret General Hospital and Seashore Imaging, LLC

144. Expert Opinions for Onslow MRI, LLC CON Application – Daniel Carter (with the exception of opinions which do not corroborate testimony)

145. Chart: Rebuttal to Agency Exhibit 12

JDI Exhibits

The following documents were offered by JDI and admitted into evidence:

5. Calculation: CAGR – 12.16%

7. Required State Agency Findings dated 2/26/09 issued to Mecklenburg Diagnostic Imaging, LLC, Project I.D. No. F-8237-08

10. Required State Agency Findings dated 11/14/09 issued to Lenoir Imaging, LLC and Lenoir Memorial Hospital, Inc., Project I.D. No. P-8147-08

11. Letter dated 6/17/09 to Lee Hoffman from Elizabeth D'Angelo regarding Response to Opposing Comments

12. Calculation: CAGR – 13.76%

14. Declaratory Ruling issued to Cape Fear Diagnostic Imaging, Inc.

16. Chart: Mortality Statistics Summary for 2006 North Carolina Residents – Heart Disease; Chart: Mortality Statistics Summary for 2007 North Carolina Residents – Heart Disease; Chart: Mortality Statistics Summary for 2008 North Carolina Residents – Heart Disease

17. Calculation: CAGR – 9.72%

18. Required State Agency Findings dated 7/30/03 issued to Coastal Carolina Health Care, P.A. d/b/a Coastal Carolina Imaging, Project I.D. No. P-6764-03; Eastern Carolina Internal Medicine, P.A. d/b/a ECIM, Project I.D. No. P-6757-03; Jacksonville Diagnostic Imaging, Project I.D. No. P-6759-03; and Craven Regional Medical Authority d/b/a Craven Regional Medical Center, Project I.D. No. P-6766-03

19. Required State Agency Findings dated 1/30/09 issued to Rex Hospital, Inc., Project I.D. No. J-8169-08; Orthopaedic Surgery Center of Raleigh, LLC, Group I Ventures ASC LLC, ASC JV LLC, Rex Orthopedic Ventures, LLC and Rex Hospital, Inc., Project I.D. No. J-8170-08; Blue Ridge Day Surgery Center, L.P. d/b/a Blue Ridge Surgery Center and Surgical Care Affiliates, LLC, Project I.D. No. J-8177-08; WakeMed & WakeMed Property Services, Project I.D. No. J-8179-08; WakeMed & WakeMed Property Services, Project I.D. No. J-8180-08; WakeMed, Project I.D. No. J-8181-08; Southern Surgical Center, LLC and Southern Surgical Building, LLC, Project I.D. No. J-81-82-08; and Holly Springs Hospital, LLC and Novant Health, Inc., Project I.D. No. J-8190-08

21. Required State Agency Findings dated 12/14/04 issued to North Carolina Baptist Hospital, Project I.D. No. G-7082-04; and High Point Regional Health System, Project I.D. No. G-7091-04

24. Outline Expert Opinions to be offered at Deposition, David Meyer, 25 February 2010 (with the exception of opinions which do not corroborate testimony)

25. Chart: New Providers in MRI Service Area

26. Required State Agency Findings dated 2/2/07 issued to New Hanover Regional Medical Center, Project I.D. No. O-7652-06; The Outpatient Surgery Center of Wilmington, LLC and ATOR Properties, LLC, Project I.D. No. O-7670-06; Same Day Surgery Center New Hanover, LLC, Project I.D. No. O-7671-06; and HealthSouth Wilmington Surgery Center, L.P. and Ashton Holdings, LLC, Project I.D. No. O-7672-06

27. Required State Agency Findings dated 1/3/05 issued to Cabarrus Memorial Hospital d/b/a NorthEast Medical Center, Project I.D. No. F-7086-04; Cabarrus Radiologists, P.A., Project I.D. No. F-7088-04; RoMedical Care, P.A., Project I.D. No. F-7092-04; Stanly Memorial Hospital, Project I.D. No. F-7084-04; and Carolinas Imaging Center, LLC, Project I.D. No. F-7085-04

28. Required State Agency Findings dated 10/14/05 issued to Southeastern Radiology, P.A., Project I.D. No. G-7267-05; Cornerstone Health Care, P.A., Project I.D. No. G-7269-05; and Triad Imaging, Inc., Project I.D. No. G-7276-05

29. Chart: Net Revenue Year 3

32. Chart: Testimony of Kathryn M.T. Platt, 2002 through 2009 and C.V. of Kathryn M.T. Platt

33. Opinions of Kathryn M.T. Platt (with the exception of opinions which do not corroborate testimony)

34. Charts: Corrected Patient Origin Analysis for JDI; Meaningful Patient Origin Analysis; Summary of Analyst's Inaccurate Growth Rate Assumptions and Corrected Growth Factors; CDI Projected Service Area Demand With Modification for Project Years; comparison of Market Demand and Impact on Market; Percentage of Total Procedures with Contrast for Keystone Planning Group Clients and Statewide; Analysis of Contractual Allowance; Analysis of Payor Mix; Classification of Payor Sources; Flaws in Table 22 & Corrected Table 22; and Response to Exhibit 33, Percentage of Total Procedures with Contrast for Keystone Planning Group Clients and Statewide

35. C.V. of Michael McLaughlin, M.D.

36. Documents produced by Onslow MRI, LLC (OMLLC: 827-833)

37. C.V. of Walter Lindstrand, R.T. (R)(MR)(CT)

40. Documents produced by Onslow Memorial Hospital, Inc. (Onslow Mem: 11-15, 29, 44, 56, 79-80, 89, 92, 97, 129, 139 and 191

45. C.V. of Daniel R. Carter, Jr.

46. Required State Agency Findings dated 3/5/08 issued to Novant Health, Inc. and Medical Park Hospital, Project I.D. No. G-7980-07 and North Carolina Baptist Hospital and Davie County Emergency Health Corporation d/b/a Davie County Hospital, Project I.D. No. G-7984-07

48. Required State Agency Findings dated 10/3/08 issued to Mecklenburg Diagnostic Imaging, LLC d/b/a North Carolina Diagnostic Imaging – Mooresville, Project I.D. No. F-8102-08; Carolina NeuroSurgery & Spine Associates, P.A., Project I.D. No. F-8106-08; and Marquis Diagnostic Imaging of North Carolina, LLC d/b/a Marquis Diagnostic Imaging of Asheville, Project I.D. No. B-8111-08

50. Required State Agency Findings dated 3/16/09 issued to Carolina Orthopaedic Specialists, P.A., Project I.D. No. E-8230-08

51. Required State Agency Findings dated 5/2/07 issued to Crystal Coast Radiation Oncology, P.A., Project I.D. No. P-7752-06; and Onslow Radiation Oncology, LLC, Onslow County and Onslow Hospital Authority, Project I.D. No. P-7769-06

52. Required State Agency Findings dated 11/29/07 issued to Johnston MRI and Johnston Memorial Hospital Authority, Project I.D. No. J-7900-07; and Johnston County Imaging, LLC d/b/a Raleigh Radiology Clayton, Project I.D. No. J-7893-07

53. PowerPoint Presentation entitled "North Carolina Certificate of Need, Your role in the $3 billion CON industry," prepared by Daniel Carter for the Health Care Industry Conference, June 18, 2009

56. C.V. of Karen L. Sandlin

58. CON Application of Lenoir Memorial Hospital, Inc., Project I.D. No. P-8147-08 and Agency File

61. Chart: Available Funds Shortfall Calculation

63. Documents Produced by Onslow MRI, LLC (OMLLC: 15-16)

66. Respondent's Objections and Responses to Petitioner's First Set of Interrogatories and First Request for Production of Documents

79. Deposition Transcript of Bernetta Thorne-Williams, Vol. 3, dated 2/8/10 (pp. 158-159)

93. Deposition Transcript of Daniel Carter dated 4/22/10 (p. 133)

95. Deposition Transcript of Karin Sandlin dated 4/30/10 (pp. 98-99)

96. Porters Neck Imaging, LLC Competitive Comments Response 2005 MRI Review, O-7254-05

97. Chart: Payor Mix Comparison of Exhibit 36

98. Chart: Market Share/Inmigration Calculation

99. Chart: Contrast Weighting

100. Chart: Contrast Comparison with other Providers

101. Chart: Analysis of Agency Ex. 13

102. Chart: Corrected only Agency's percentage increase keeping all other Agency assumptions constant

<u>**Agency's Exhibits**</u>

8. 2009 State Medical Facilities Plan

11. Responsive Comments filed by Onslow MRI dated June 15, 2009

12. Rebuttal Exhibit re: OMLLC

13. Rebuttal Exhibit re: JDI

EXHIBITS SUBMITTED AS OFFERS OF PROOF

OMLLC Exhibits

111. Spreadsheet: Eastern Radiologists Balance Sheet

140. Chart: Contrast Use in < 1.5T scanners vs. 1.5T MRI scanners operated by Radiologists

JDI Exhibits

44. Chart: MedQuest MRI Contrast Report – 1.5T Scanners – North Carolina Region, Dates of Service: 1/1/2009 – 12/31/2009

STIPULATIONS REGARDING THE JDI APPLICATION

On May 14, 2010, JDI and the Agency entered into the following written stipulations concerning the Agency's decision on the JDI Application. These stipulations were filed in OAH on May 18, 2010.

1. The Agency's Table 6 on page 519 of the Agency File contains a mistake. The accurate compound annual growth rate (CAGR) is 13.76%, which is what the applicant had in its application. The Agency's correction to 12.16% (CAGR) is inaccurate.

2. The Agency's Table 10 on page 523 of the Agency File contains data entry errors, which lead to the wrong conclusion. Specifically, the Agency erred in stating on page 524 that "This indicates a 1.8% decrease in those Onslow County patients who received MRI procedures at CDI in fiscal year 2008." Corrected data shows that CDI's percent patient origin from Onslow County actually *increased* by 0.39%.

CDI MRI Patient Origin Comparison 2007 to 2008					
	2007 # of Patients	2007 % Patient Origin	2008 # of Patients	2008 % Patient Origin	Change in % Patient Origin
Onslow	2,831	[illegible]	3,263	85.20%	[illegible]
Carteret	69	[illegible]	104	2.70%	0.63%
Craven	57	[illegible]	77	2.00%	0.29%
Duplin	108	[illegible]	115	3.00%	-0.24%
Jones	[illegible]	[illegible]	102	2.70%	0.03%
Lenoir	17	[illegible]	28	0.70%	0.19%
Pender	51	[illegible]	52	1.40%	-0.13%
Other Counties	[illegible]	[illegible]	54	1.40%	-0.88%
Other States	[illegible]	[illegible]	36	0.90%	-0.30%
Total	[illegible]	[illegible]	3,831	100.00%	

3. The Agency's analysis on page 526 of the Agency File contains a mistake. Specifically, the Agency erred by stating "In FY2008 CDI served 2,614 Onslow County residents. Thus, in PY1, the applicants are projecting a 223% increase in Onslow County residents who are projected to have scans performed at CDI." The Agency pulled Onslow Memorial Hospital's numbers for this analysis and statement. As shown on page 165 of the Agency File, JDI/CDI served 3,263 patients from Onslow County in FY 2008.

4. The Agency's reference on page 528 of the Agency File to a CAGR of 12.16% is a mistake. *See* Stipulation 1, above.

5. On page 528 of the Agency File, the Agency erred by not accepting JDI's representation that one third of JDI's patient population is military and further erred in stating that "[t]herefore, it is just as likely that those seeking MRI services not offered at the Naval Hospital Camp Lejeune would opt to receive those services at Onslow Memorial Hospital which is closer to the military base than the services proposed by CDI."

6. A 1:1 correlation between the volume projections and the number of estimated referrals in the physician letters of support is not required.

7. If the Agency had found JDI conforming to Criterion 3, it would also have found JDI conforming with Criteria 4 and 6.

8. Although the Agency stated on page 555 of the Agency File that "it is unclear how much of the proposed project will be financed by MedQuest's accumulated reserves or through Novant Health, Inc.'s revolving Line of Credit. Therefore, it is impossible to determine if the applicant has accounted for all related expenses;" nonetheless, the Agency concluded that CDI had demonstrated availability of funds.

9. On page 556 of the Agency File, the Agency erred in concluding that JDI did not include professional fees in its performance standards.

10. The Agency erred by stating that JDI's charges are not global and professional fees are not included in the pro forma financial projections.

11. If the Agency had found JDI conforming with Criteria 1, 3, 4, 5, 6, and 13c, it would have found JDI conforming with Criterion 18a.

12. The Agency's finding on page 587 of the Agency File that JDI was non-conforming with 10A NCAC 14C.2702(c)(8) was erroneous.

13. The Agency's finding on page 589 of the Agency File that JDI was non-conforming with 10A NCAC 14C.2702(c)(9) was erroneous.

BASED UPON careful consideration of the sworn testimony of the witnesses presented at the hearing, the documents and exhibits received and admitted into evidence, and the entire record in this proceeding, the Undersigned makes the following Findings of Fact. In making the

Findings of Fact, the Undersigned has weighed all the evidence and has assessed the credibility of the witnesses by taking into account the appropriate factors for judging the credibility, including but not limited to, the demeanor of the witnesses, any interests, bias, or prejudice the witness may have, the opportunity of the witness to see, hear, know, or remember the facts or occurrences about which the witness testified, whether the testimony of the witness is reasonable, and whether the testimony is consistent with all other believable evidence in the case.

FINDINGS OF FACT

1. The Certificate of Need Section ("CON Section" or the "Agency") is the agency within the N.C. Department of Health and Human Services (the "Department"), the Division of Health Service Regulation (the "Division") that carries out the Department's responsibility to review and approve the development of new institutional health services under the Certificate of Need ("CON") Law, codified at N.C. Gen. Stat. Chapter 131E, Article 9.

2. A CON is required for certain "new institutional health services" as that term is defined by N.C. Gen. Stat. § 131E-176(16). Subsection (f1) of this statute requires a person or entity acquiring a MRI "by purchase, donation, lease, transfer, or comparable arrangement" to first obtain a CON. N.C. Gen. Stat. § 131E-176(16)(f1).

3. The acquisition of a MRI is *per se* reviewable under the CON Law. *See* N.C. Gen. Stat. § 131E-176(16)(f1), and are subject to the methodologies and need determinations contained in the applicable State Medical Facilities Plan ("SMFP").

4. The State Medical Facilities Plan ("SMFP") is the official plan developed and published each year which inventories current services, facilities and equipment that are subject to CON regulation as well as the utilization of those services, facilities and equipment, and

projects future needs for additional services, facilities and equipment in each service area. N.C. Gen. Stat. § 131E-176(25).

5. The SMFP is developed under the direction of the State Health Coordinating Council ("SHCC"), which is comprised of health care professionals and other citizens each of whom is appointed by the Governor with the approval of the Senate. N.C. Gen. Stat. §§ 131E-176(17), (25); -177(4). The SHCC submits a recommended SMFP for review by the Governor who has the ultimate authority to approve and finalize the SMFP. N.C. Gen. Stat. § 131E-176(25).

6. The 2009 SMFP, which applies to both of the CON applications filed in this Review, included a need determination for one fixed MRI in Onslow County. (Agency Ex. 8)

7. On April 15, 2009, Onslow MRI, LLC ("OMLLC") filed a CON application with the CON Section seeking to develop a new diagnostic center and to acquire a fixed MRI scanner in Onslow County, North Carolina, identified as Project I.D. No. P-8332-09 ("OMLLC Application"). (Jt. Ex. 3)

8. OMLLC is a new North Carolina limited liability company with the sole member being EC Rad, LLC. EC Rad LLC has two member, Eastern Radiologists, Inc. ("ERI") and CoRad ("Coastal Radiologists, PLLC") Investments, LLC. (Jt. Ex. 3 at 5)

9. On April 15, 2009, Jacksonville Diagnostic Imaging, L.L.C., d/b/a Coastal Diagnostic Imaging ("JDI") also filed a CON application with the CON Section to acquire a fixed MRI scanner for an existing facility in Onslow County, North Carolina, identified as Project I.D. No. P-8326-09("JDI Application") (Jt. Ex. 2)

10. JDI is a North Carolina limited liability company with only one member, Triad Imaging, LLC, a North Carolina limited liability company. Medquest, Inc., a Delaware

corporation is the sole member of Triad Imaging, LLC. MQ Associates, Inc., a subsidiary of Novant Health, Inc. is the sole stockholder of Medquest, Inc. (Jt. Ex. 2 at 5)

11. Project Analyst, Bernetta Thorne-Williams and Team Leader, Helen Alexander were the employees of the Agency who reviewed the OMLLC Application and the JDI Application. (Alexander Tr., Vol. 11, pp. 2110-2111)

12. On May 1, 2009, as scheduled under the SMFP, the Agency began its review of these applications (the "Review"). The Agency determined that the Review was competitive because the 2009 SMFP identified a need for only one additional fixed MRI scanner in Onslow County and, thus, at most only one fixed MRI scanner could be approved in the Review. (Jt. Ex. 1 at 5, 20)

13. Even when there is a need determination in the SMFP, the Agency cannot approve an application unless the applicant demonstrates it is conforming or conditionally conforming to the applicable review criteria. *See* N.C. Gen. Stat. § 131E-183.

14. The applicant has the burden of demonstrating conformity with the review criteria. *Presbyterian-Orthopaedic Hosp. v. N.C. Dep't of Human Res.*, 122 N.C. App. 529, 534, 470 S.E.2d 831, 834 (1996).

15. The Agency "batched" the two applications, and determined whether each individual application standing alone conformed to applicable statutory and regulatory review criteria. N.C. Gen. Stat. § 131E-183(a).

16. To receive a CON for a proposed project, each applicant's proposal must satisfy all applicable statutory review criteria specified in N.C. Gen. Stat. § 131E-183(a) as well as all applicable regulatory review criteria established pursuant to N.C. Gen. Stat. § 131E-183(b). N.C. Gen. Stat. § 131E-183; *Bio-Medical Applications of N.C., Inc.*, 136 N.C. App. 103, 523

S.E.2d 677 (1999); *Presbyterian-Orthopaedic Hosp.*, 122 N.C. App. 529, 534-35, 470 S.E.2d 831, 834 (1996).

17. During the Review, OMLLC filed written comments asserting that the JDI Application should be disapproved. JDI also filed written comments, asserting that the OMLLC Application should be disapproved. (Agency Ex. 11) (Jt. Ex. 1 at 30-72)

18. The public hearing was held on June 17, 2009. Representatives of OMLLC and JDI presented information at the public hearing regarding their respective application as well as the competing application. (Jt. Ex. 1 at 73-92; 93-116)

19. By decision letter dated September 22, 2009 and the Required State Agency Findings issued September 22, 2009 (the "Findings"), the CON Section disapproved the OMLLC Application. (Jt. Ex. 1 pp. 27-29; Jt. Ex. 1, pp. 504-613)

20. By decision letter dated September 22, 2009 and the Required State Agency Findings issued September 22, 2009 (the "Findings"), the CON Section disapproved the JDI Application. (Jt. Ex. 1 at 12-14; Jt. Ex. 1, pp. 504-613)

21. On October 15, 2009, OMLLC filed a Petition for Contested Case Hearing challenging the disapproval of its Application.

22. On October 16, 2009, JDI filed a Petition for Contested Case Hearing challenging the disapproval of its Application.

23. On October 19, 2009, OMLLC and JDI filed a Joint Consent Motion to Intervene and Petition to Consolidate in the contested cases.

24. On October 28, 2009, the joint motion to intervene and the petition to consolidate were granted.

I. THE OMLLC APPLICATION

The Agency found the OMLLC Application non-conforming with Statutory Review Criteria 1, 3, 4, 5, 6, 7, 8, 18a, and with Regulatory Review Criteria 10A N.C.A.C.14C.2703(b)(3) (Jt. Ex. 1, pp. 504-607)

A. STATUTORY REVIEW CRITERIA

1. CRITERION 1

G.S. § 131E-183(a)(1) ("Criterion 1") provides as follows:

> 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.

25. The Agency found that although the OMLLC Application is consistent with the SMFP need determination, it is nonconforming with Policy GEN-3 and therefore is nonconforming with Criterion 1. (Jt. Ex. 1 at 511)

26. The Agency concluded that the OMLLC application is consistent with the need determination for fixed MRIs in the 2009 SMFP. (Jt. Ex. 1 at 511)

27. Policy GEN-3 requires a CON application to: (1) promote safety and quality; (2) promote equitable access; and (3) maximize health care value. (Alexander Tr., Vol. 11 at 2115)

28. The Agency found that OMLLC did not adequately demonstrate the need for its proposed project under Criterion 3, and did not demonstrate that its project is financially feasible under Criterion 5; and, based on the same reasoning, OMLLC did not demonstrate the process by which it plans to maximize healthcare value expended under Criterion 1. (Jt. Ex. 1 at 522) (Platt Tr., Vol. 8 pp. 1481-1482) Alexander Tr., Vol. 11 at 2115)

29. Had OMLLC been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 1. Thus, the Agency's finding of non-conformity under Criterion 1 for the OMLLC Application was a derivative of other findings.

30. Therefore, if the Agency erred in its determination that the OMLLC Application was non-conforming with Criteria 3 and 5, the OMLLC Application would be conforming with Criterion 1.

2. <u>CRITERION 3</u>

G.S. § 131E-183(a)(3) ("Criterion 3") provides as follows:

> 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.

31. Criterion 3 has two components: (1) the applicant must identify the population that it proposes to serve and (2) the applicant must demonstrate the need that population has for the services it proposes.

a. Population Proposed to Be Served

32. The Agency appropriately found that the OMLLC Application adequately identified the population to be served by the proposed project. (Jt. Ex. 1 at 531)

b. Need for the Proposed Project

33. The Agency found that the OMLLC Application did not adequately demonstrate the need the population it proposes to serve has for the proposed fixed MRI. (Jt. Ex. 1 at 552)

34. In its findings, the Agency noted that the OMLLC Application stated that the <u>need</u> for the proposed fixed MRI scanner was based on the following factors: the 2009 SMFP Need

Determination; Projected Population Growth/Aging Population; Income per Capita; Cancer Incident Rate; Heart Disease Rate; and MRI Utilization Rate. (Jt. Ex. 1 at 531)

35. The Agency contends that OMLLC did not provide a specific methodology for which the annual MRI projections were based on the growing population Onslow County over the age of 65. Therefore, the Agency contends the growth in population in the over 65 age population, by itself did not support the applicants projections. (Jt. Ex. 1 at 533)

36. Likewise, the Agency contends OMLLC did not include any assumptions or methodology to demonstrate the number of MRI scans it projects to perform in the detection of cancer incidents procedures for Onslow County residents, and, therefore, the applicant's use of MRI technology in the detection of cancer did not support the projected number of MRI scans. (Jt. Ex. 1, at 535)

37. The Agency contends OMLLC did not include any projections for breast and cardiac MRI procedures, and, therefore, the applicant's proposal to offer breast and cardiac imaging capability did not support the projected number of MRI scans. (Jt. Ex. 1, pp. 537-39)

38. The Agency did not find a similar failure on the part of OMLLC to base its volume projections upon or provide a methodology based upon either of the other two listed factors, i.e., the "2009 State Medical Facilities Plan (SMFP) Need Determination" or "Income per Capita" factors. See Joint Ex. 1, Agency File, pp. 531-533.

39. Each of these factors cited by the Agency was discussed in the OMLLC Application at length from the qualitative perspective. Joint Ex. 3, OMLLC App., pp. 41-57.

40. David Meyer is the president of Keystone Planning Group and an accepted expert in health planning and CON application preparation and analysis. He was one of the primary authors of the OMLLC Application, and he testified that the methodology was not empirically

based upon these qualitative factors, drawing a distinction between the qualitative and quantitative factors. (See Sandlin, Tr. pp. 83-85, 98-100; Meyer, Tr. pp. 366-79; also see OMLLC Ex. 104, CV of David Meyer; and accord JDI Ex. 24, Deposition Opinions of David Meyer, pp. 1-2). Mr. Meyer testified that the quantitative methodology for projecting need for the project did not begin until page 57 of the application, under the heading "Methodology for Projecting OMLLC MRI Utilization." (Joint Ex. 3, OMLLC App., p. 57; also see Sandlin, Tr. pp. 83-85, 98-100; Meyer, Tr. pp. 365-67, 513).

41. Keystone Planning Group partner Ms. Karin Sandlin, also an accepted expert in health planning and CON application and analysis, was the author of Sections I through V of the OMLLC Application. (See Sandlin, Tr. pp. 64; also see JDI Ex. 51, CV of Karin Sandlin). Ms. Sandlin mirrored the testimony of Mr. Meyer, pointing to pages 41-56 of the OMLLC Application as being a discussion of the qualitative need for the project, intended to provide context for the application. Ms. Sandlin pointed to the narrative found on pages 57-72 of the application as the actual methodology used to demonstrate the need for the project. (See Sandlin, Tr. pp. 83-85, 98-100; Meyer, Tr. pp. 365-67, 513; compare and accord Joint Ex. 3, OMLLC App., pp. 41-72).

42. Both Mr. Meyer and Ms. Sandlin pointed out that the OMLLC Application answered both questions III.1.(a) and III.1.(b) in Section III together in one narrative. Both testified that based upon their education, experience, and expertise, question III.1.(a) is generally regarded as calling for a discussion of qualitative need while question III.1(b) calls for a discussion of quantitative / statistical or empirical need. (See Sandlin, Tr. pp. 83-85; Meyer, Tr. pp. 365-67; compare Joint Ex. 3, OMLLC App., p. 41).

43. OMLLC's Application clearly draws a distinction in its presentation on page 57 with the heading Methodology for Projecting OMLLC MRI Utilization which supports the contentions of Mr. Meyer and Ms Sandlin. The Agency Findings do not seem to show such delineation between the quantitative and qualitative portions of the application.

44. Ms. Alexander explained that the Agency looks for a link between qualitative demographic information in an application to the specific assumptions and methodology of the projections. OMLLC provided information about the population of Onslow County, the income per capita, and the incidence of cancer and heart disease, as part of the narrative for the qualitative consideration and not as part of the quantitative. Therefore, OMLLC contends that it purposefully did not provide a link between that qualitative information and their methodology.

45. However, on page 59 of the quantitative analysis, OMLLC purports to base its market share on the following factors: offering cardiac and breast MRI capabilities not currently available in Onslow County; MRI is a proven and effective tool in the diagnosis and treatment of cancer; increasing access to MRI services for obese and claustrophobic patients; 24 physician support letters; establishing the first freestanding, dedicated outpatient 1.5T fixed MRI scanner owned by local physicians in Onslow County; and offering a new, freestanding non-hospital-based MRI service in Onslow County. (Jt. Ex. 1 at 548)

46. OMLLC did not use these six identified factors in a methodology to support its projected market share. OMLLC does not tell us how many cardiac or breast MRI procedures it projects to perform; how many scans to detect or treat cancer it projects to perform; how many obese and claustrophobic patients it projects to serve; or specifically how the physician letters or the fact that they will be a new provider owned by physicians will affect their market share.

47. There is no specific requirement for demographic trends, such as the population over the age of 65 to be specified in the utilization projections. (Carter Tr., Vol. 13 at 2052).

48. JDI's expert, Kathryn Platt, offered that she has quantified breast and cardiac MRI procedures in CON's for MedQuest in the past. (Platt Tr., Vol. 8, pp. 1504-1505).

49. Ms. Alexander testified that if information about various factors is critical to demonstrating the applicant's projection, there must be a connection between the data provided and the methodology used to project utilization. Further, Ms. Alexander testified that as a new provider with no market share the applicant did not demonstrate any connection between cancer incidents, cardiac disease, and risk factors for breast cancer and the number of MRI procedures projected. (Alexander Tr., Vol. 11 at 2124).

50. If qualitative or quantitative information is critical to showing that an applicant's projections are reasonable, then the applicant must link that data to their assumptions and methodology. OMLLC could have linked the qualitative and/or quantitative demographic information provided in its application to specific assumptions and methodology in an attempt to justify their projections, but did not. The factors OMLLC identified could have demonstrated the need; however, OMLLC chose not to utilize these factors in making its projections. (Alexander Tr., Vol. 11 at 2121-24)

i. Service Area Projections

51. As stated, the empirical methodology for projecting need for the OMLLC facility begins on page 57 of the OMLLC Application. <u>See</u> Joint Ex. 3, OMLLC App., pp. 57; Sandlin, Tr. pp. 83-85, 98-100; Meyer, Tr. pp. 365-67, 513. Both Mr. Meyer and Ms. Sandlin testified that the methodology used was based upon (1) a projection of the growth in overall MRI scans

performed in Onslow County, and (2), OMLLC's capture of a percentage of that future Onslow County MRI market share. See id.

52. In the first part of that methodology, OMLLC projected that the number of MRI scans performed in Onslow County would grow annually by 8.14%, based upon the compound annual growth rate ("CAGR") for the 5-year period between FY 2003 and FY 2008. Joint Ex. 3, OMLLC App., p. 57.

53. CAGR is a commonly-used method of projecting growth in demand for health services, as it tends to smooth out anomalies that can be found from year to year. See Thorne-Williams, Tr. pp. 633,639-41; Alexander, Tr. pp. 2125-28, 2244-45; Meyer, Tr. pp. 381-83; Carter, Tr. pp. 2069-70; Sandlin, Tr. pp. 121-23.

54. Based upon the above growth rate, OMLLC projected that the following number of un-weighted outpatient MRI scans would be performed in Onslow County in FY 2012-2014; 8,873 in FY 2012, 9,595 in FY 2013, and 10,377 in FY 2014, Joint Ex. 3, OMLLC App., p. 58.

55. Because OMLLC projected that the first three years of the project would be calendar years 2011-2013, the OMLLC Application converted the above projections to calendar years, such that the projected total number of MRI scans performed in Onslow County during those years would be as follows: 8,371 in CY 2011, 9,053 in CY 2012, and 9,790 in CY 2013. Id.

56. The Agency found that OMLLC's projected 5-year CAGR was unsupported and unreliable, because it did not correctly reflect the growth in MRI procedures in Onslow County between FY 2003 and FY 2008. Joint Ex. 1, Agency File, p. 544. However, when corrected, the actual 5-year CAGR for MRI procedures was 9.96%. Joint Ex. 1, Agency File, p. 541. Performing a separate analysis, the Agency found that the 5-year CAGR in Onslow County was

9.72%. Therefore, under either circumstance, OMLLC's projected growth rate was reasonable, because it was lower (and therefore more conservative) than the Agency's projected growth rate.

57. The Agency Findings also questioned OMLLC's 5-year CAGR because it was higher than the 2-year CAGR for the same service area. Joint Ex. 1, Agency File, p. 544.

58. The Agency calculated that while the five-year Compounded Annual Growth Rate ("CAGR") for Onslow County un-weighted outpatient MRI utilization from FY2003-FY2008 was 9.72%., it was only 5.54% for FY2006-FY2008. (Jt. Ex. 1 at 544)

59. That 2-year CAGR is less reliable than the 5-year CAGR used by OMLLC, because overall MRI usage grew very slowly between FY 2007 and FY 2008, due to the recognized recession and/or other factors. See Thorne-Williams, Tr. pp. 637-45, 1049; Alexander, Tr. pp. 2244-45; Meyer, Tr. pp. 381-84; OMLLC Ex. 144.

60. Using a CAGR is helpful in smoothing out a rather linear curve over a 5 year period. It is recognized that there was a significant increase in the percent change in MRI services performed in Onslow County after JDI acquired a fixed MRI in late 2006 and that when JDI reached capacity on the machine, the percent change leveled off.

61. The Agency Findings offered no explanation as to why a 2-year CAGR is more reasonable to use than a 5-year CAGR, and the Agency witnesses could not provide one during the contested case hearing. See Joint Ex. 1, Agency File, pp. 544; Thorne-Williams, Tr. pp. 637-45, 1049; Alexander, Tr. pp. 2244-45.

62. OMLLC reasonably relied upon a 5-year CAGR to project the growth in MRI procedures in Onslow County.

ii. Market Share Assumptions

63. The OMLLC Application projected that it would capture 25% of the market for MRI scans in Onslow County in Project Year 1. In Project Year 2, its projected market share would be 33.3%, and by Project Year 3, its projected market share would be 36.3%. (Jt. Exh. 3, p. 59)

64. OMLLC projected to perform 2,093 MRI procures in its first year, to increase that number by 44.1% during the second year and to perform 3,558 procedures by the third year. The Agency concluded that a 70% increase over three years was unreasonable given the historical data for Onslow County MRI procedures. (Jt. Ex. 1 at 541-42)

65. In addition, even though OMLLC projected to serve only Onslow County patients, their projections were based upon historical numbers that included all patients who had MRI procedures in Onslow County from FY2003-FY2008. As a result of including patients other than Onslow County residents in their base, the Agency contends that OMLLC's projections were necessarily inflated. (Jt. Ex. 1, pp. 543-44, 547) (Alexander Tr., Vol. 11 pp. 2130-31, 2139-2142)

66. The Agency found that "[t]he applicant did not adequately demonstrate that the assumptions used to project market share at a new facility account for the available capacity of the existing MRI scanners in Onslow County, particularly the under utilized MRI scanner at OMH." (Jt. Ex. 1, p. 548)

67. The OMLLC Application projected an outpatient market share equal to the OMLLC percent of total scanners in Onslow County when approved, or 1 of 3 scanners, or 33.3%. The existing MRI providers in Onslow County, JDI and Onslow Memorial Hospital, do not currently split the available market. (Platt, Vol. 8, pp. 1505-1506) Another factor affecting

the market is that approximately 27 percent of the patients in the county are leaving the county for MRI. (Platt, Vol. 8, pp. 1505-1506)

68. OMLLC purports to base its market share on the following factors: offering cardiac and breast MRI capabilities not currently available in Onslow County; MRI is a proven and effective tool in the diagnosis and treatment of cancer; increasing access to MRI services for obese and claustrophobic patients; 24 physician support letters; establishing the first freestanding, dedicated outpatient 1.5T fixed MRI scanner owned by local physicians in Onslow County; and offering a new, freestanding non-hospital-based MRI service in Onslow County. (Jt. Ex. 1 at 548)

69. OMLLC contends that the physician letters of support in its application contained information regarding the number of breast imaging MRI scans which may be performed. Other physician letters generally discussed the need for breast MRI in Onslow County, and their intent to refer patients to the OMLLC MRI for this service. See generally, Joint Ex. 3, OMLLC Application, Exhibit 17.

70. While OMLLC did include 24 physician letter of support, OMLLC did not use the letters in a methodology to support the projected market share. In addition, although OMLLC projected to serve only Onslow County residents, the physician letters included patients from outside of Onslow County. (Alexander Tr., Vol. 11 pp. 2147-48) (Jt. Ex. 1 at 551)

71. Although the applicant proposed to perform cardiac imaging, three Onslow County cardiologists declined to provide letters of support. (D'Angelo Tr., Vol. 10 at 1885-1886)

72. At trial, OMLLC's expert witness, David Meyer, correctly points out that OMLLC was not required to provide volumes for breast and cardiac scans. (Meyer, Vol. 3, p.

510) Mr. Meyer acknowledged that OMLLC was not precluded from including volume projections for breast and cardiac scans. (Meyer, Vol. 3, p. 511)

73. An applicant can include whatever it wants to include in its application to demonstrate the need for its project, even if the Agency does not expressly request the information. (Meyer, Vol. 3, p. 425)

74. Mr. Meyer could not recall any new MRI providers that obtained a 25% market share in MRI scans in one year after opening where there were already two other providers of MRI in that same county. (Meyer, Vol. 3, p. 536)

75. Mr. Daniel Carter, OMLLC's expert witness, testified that based on his experience, it is fair to say that new entrants to a market often require a ramp-up period before they get established. (Carter, Vol. 11, p. 2016) Mr. Carter did not know and had not done any analysis of any new provider that had been able to achieve a 25% market share one year after opening when the new entrant was coming into a market that already had two existing scanners. (Carter, Vol. 10, pp. 1992-1993)

76. The Agency concluded that "despite a growing population, the use of MRI procedures has slowed in both the State of North Carolina and Onslow County; and, therefore, it is unreasonable for the applicant to assume, that as a new provider of MRI services in the proposed service area with an underutilized fixed MRI scanner in OMH, that it will receive 33.3% of the market share by its second year of service and 36.3% by the third year of service." (Jt. Ex. 1, at 552)

77. OMLLC failed to use the six factors identified in its quantitative analysis in a methodology to support its projected market share. OMLLC does not tell us how many cardiac or breast MRI procedures it projects to perform; how many scans to detect or treat cancer it

projects to perform; how many obese and claustrophobic patients it projects to serve; or specifically how the physician letters or the fact that they will be a new provider owned by physicians will affect their market share. Therefore, the Agency properly concluded that OMLLC's market share projections were unsupported and unreliable. (Jt. Ex. 1 at 549)

iii. Significance of Prior Agency Decisions

78. Much of OMLLC's argument rests on the comparison between the current application and a prior application for Lenoir Imaging LLC.

79. All of the health planning experts tendered and accepted by the Court during the contested case hearing agreed that, aside from the Statutory Review Criteria and Agency Rules, past Agency decisions, reflected in the CON Section's Required State Agency Findings, are the only substantive source of guidance that potential applicants have with regard to what the Agency expects and how it will address specific issues. See Sandlin, Tr. pp. 55-220; Meyer, Tr. pp. 297-98; Platt, Tr. pp. 1987-88; Carter, Tr. pp. 2085-86.

80. Both Ms. Thorne-Williams and Ms. Alexander acknowledged that applicants do rely upon past sets of Agency Findings and the Agency often suggests that applicants review specific sets of findings to learn more about the Agency's treatment of a specific set of issues or circumstances. See Thorne-Williams, Tr. pp. 560-62, 590.

81. Consistency in its decisions is very important to the Agency. See Thorne-Williams, Tr. pp. 560-561, 687.

82. Ms. Sandlin testified that she drafted the need and methodology discussion found in Section III of the OMLLC Application based upon a structure she had previously used or seen used in numerous other CON Applications. See Sandlin, Tr. pp. 86-90; accord Joint Ex. 3, OMLLC App., pp. 41-72.

83. In particular, Ms. Sandlin pointed to the previous application prepared by Keystone Planning Group and submitted to the Agency on behalf of Lenoir Imaging, LLC, on 16 June 2008 (hereinafter the "Lenoir Application"), which—like the OMLLC Application—also proposed to develop a freestanding outpatient MRI facility. See Sandlin, Tr. pp. 86-90; JDI Ex. 58, Lenoir Application. Both Ms. Sandlin and Mr. Meyer pointed to the numerous structural and substantive similarities between the OMLLC Application and the Lenoir Application, noting that in many areas the two were essentially word-for-word duplicates. See Sandlin, Tr. pp. 90-99; Meyer, Tr. pp. 367-68; and compare Joint Ex. 3, OMLLC App., pp. 41-72 and JDI Ex. 58, pp. 46-69.

84. The Lenoir Application was ultimately approved by the Agency on 14 November 2008—only 152 days prior to the OMLLC Application being submitted on 15 April 2009 and only 312 days before the issuance of the Agency Findings at issue in the instant case on 22 September 2009. Compare JDI Ex. 10, Agency Findings: Lenoir Imaging, LLC (Project I.D. No. P-8147-08), p. 1; Joint Ex. 1, Agency File, p. 504; Joint Ex. 3, OMLLC App., p. 1.

85. Both the findings related to the Agency review of the Lenoir Application (hereinafter the "Lenoir Findings") and the Agency Findings in the case at bar were prepared by CON Section project analyst Bernetta Thorne-Williams and were reviewed by CON Section team leader Helen Alexander. Compare JDI Ex. 10, p. 1; Joint Ex. 1, Agency File, p. 504.

86. The Lenoir Findings, however, contain no discussion of the failure of the applicant to identify specific volumes of procedures tied to the qualitative factors cited in the Lenoir Application being supportive of the need projections for the proposal. See JDI Ex. 10, pp. 6-23; Thorne-Williams, Tr. pp. 590, 594-595.

87. In contrast to the Lenoir Findings, in the instant review, the Agency found that the discussions in the application related to qualitative need factors—independent of the empirical methodology—rendered the methodological need, volume, and utilization projections unreliable. See id.

88. Ms. Thorne-Williams and Ms. Alexander acknowledged that there were similarities between Lenoir Review and the Onslow Review, but pointed to differences between the two as the reason for the approval of the Lenoir Application and the disapproval of the OMLLC Application. A primary factor was that the Lenoir Review was a non-competitive application, which permitted the Agency to request additional information from Lenoir Imaging in order to determine conformity with Criterion 3. The Agency may not request additional information of an applicant during a competitive review, like the one at issue here. It was also pointed out that the hospital was the co-applicant in Lenoir, and that Lenoir County is a different county with a different population. See Thorne-Williams, Tr. pp. 580-81, 796; Alexander, Tr. pp. 2237-38, 2524-25.

89. Ms. Thorne-Williams had considerable difficulty explaining why she made the findings that she did in the present case concerning OMLLC as compared to Lenoir. This Tribunal notes that in her testimony Ms. Thorne-Williams was oftentimes incapable of explaining her findings or could not remember in order to justify her findings as to both applicants.

90. However, Ms. Thorne-Williams was consistent in not changing her ultimate conclusion as to the distinction between the two and that it was a matter of different counties and different populations and different applications. As such this Court notes the degree of lack of consistency between the two applications.

iv. **Contrasts**

91. Under 10A N.C.A.C. 14C .2701(18), different types of procedures are given different weight based upon the length of time required to complete the procedures. See Joint Ex. 1, Agency File, pp. 275-76; accord Sandlin, Tr. pp. 159-60; Thorne-Williams, Tr. pp. 1028-29; Platt, Tr. pp. 1484-85; Alexander, Tr. pp. 2176-77. In particular, 10A N.C.A.C. 14C .2701(18), provides in relevant part as follows:

> *...one outpatient MRI procedure without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure with contrast or sedation is valued at 1.4 weighted MRI procedures,...*

Id.

92. "Contrast," as used in 10A N.C.A.C. 14C .2701(18), refers to the process of introducing media into the human body for the purpose of obtaining more precise images of structures within the body using magnetic resonance. See Lindstrand, Tr. pp. 1094-95; Everett, Tr. pp. 1774-75. Gadolinium is the standard contrast media used in MRI procedures, which differs from the Iodinated contrast used in Computed Tomography (CT) scanning procedures. See Lindstrand, Tr. pp. 1094-95; Everett, Tr. pp. 1774-79.

93. The OMLLC Application projected that the percentage of its contrast and non-contrast procedures would mirror the historical outpatient MRI experience of Onslow Memorial Hospital. Taking the data found in Onslow Memorial Hospital's 2009 License Renewal Application, OMLLC projected that its procedure mix would be 44.68% contrast and 55.32% non-contrast. See Joint Ex. 3, OMLLC App., pp. 60-61; accord Joint Ex. 1, Agency File, p. 134.

94. OMLLC explained that the primary reason underlying its decision to project contrast based upon the experience of Onslow Memorial Hospital was due to the fact that the hospital's experience mirrored that of the physicians of Coastal Radiology Associates

(hereinafter "Coastal Radiology") who was to provide professional interpretation services at OMLLC, and which is a parent of OMLLC. See Joint Ex. 3, OMLLC App., pp. 5-8, 60.

95. Coastal Radiology has read all of the scans on the MRI at Onslow Memorial Hospital since approximately 2001. See Everett, Tr. P. 1769; D'Angelo, Tr. Pp. 1847, 1904. The mere fact that Coastal Radiology has read all of the MRI's at the hospital does not automatically translate into carrying the hospitals experience into a totally different entity.

96. OMLLC projected utilization for its proposed fixed MRI scanner would be 3,557 un-weighted MRI procedures during Project Year 3, and then projected its weighted MRI procedures based on outpatient contrast utilization at Onslow Memorial Hospital ("OMH"). OMH's outpatient procedure mix was 44.68% contrast and 55.32% non-contrast during FY2008. (Jt. Ex, 1 at 549)

97. Most MRI scans do not require contrast. (Feole Tr., Vol. 8, pp. 1318-1319) Contrast scans are more expensive than non-contrast scans. (Feole Tr., Vol. 8, p. 1322) Contrast also carries a small but real risk of adverse reactions, including death. (Feole Tr., Vol. 8, p. 1320)

98. The contrast percentage is significant in creating the MRI volume projections. Pursuant to the performance standard set forth in 10A N.C.A.C. 14C .2703(b)(3), the applicants in this review are required to meet a performance standard of 4,118 weighted MRI scans per scanner in the third project year. 10A NCAC 14C .2703(b)(3); (Jt. Ex. 1, pp. 598-99)

99. Contrast scans are given greater weight than non-contrast scans. (Agency Ex. 8, p. 139). Therefore, the more contrast scans a provider has, the easier it is for the provider to reach the performance standard of 4,118 weighted MRI scans per scanner in the third project year.

100. OMLLC stated in its application that "[b]ased on their historical experience interpreting outpatient MRI procedures at OMH, the physicians agree that 44.68% contrast utilization is as reasonable estimate for the proposed fixed MRI service." (Jt. Ex. 3, p.27)

101. However, the Coastal physicians had no role in the preparation of the application, did not provide any information to be used in the application, and were not consulted about the contrast percentage before the application was filed. (*See, e.g.*, Everett Tr., Vol. 10, pp. 1811 and 1816)

102. Although Dr. D'Angelo testified that she was "fine" with the contrast percentage of 44.68%, (D'Angelo Tr., Vol. 10, 1867), she revealed that she knew nothing about how the contrast percentage was determined. (D'Angelo Tr., Vol. 10, pp. 1869 and 1871)

103. Ms. Alexander testified that the Agency Findings incorrectly comment on page 549 that OMMLC projected inpatients weighted MRI procedures based on out- patient contrast utilization at OMH. Nevertheless, Ms. Alexander said that this error did not change the conclusion that the 44.68% contrast level was extremely high and unsupported. (Alexander Tr., Vol. 11 at 2145)

104. At hearing, there was some evidence offered by experts for OMLLC regarding why the experience at JDI would not be a good measuring stick for the projected contrast volumes at OMLLC. OMLLC was not required to base its contrast percentage on either Onslow Memorial Hospital's or on JDI's contrast percentage. (Sandlin, Vol. 1, p. 184)

105. Dr. Everett reads MRI scans for multiple facilities. (Everett, Vol. 10, p. 1841) Dr. Everett noted a "big variation" in contrast percentages across Coastal's practice. (Everett, Vol. 10, p. 1818) The various sites for which Dr. Everett reads have different percentages of contrast based on the patient population and the referring physicians. (Everett, Vol. 10, p. 1841) About

one third of the scans that Dr. Everett interprets are contrast scans. One third is obviously less than 44.68. (Everett, Vol. 10, p. 1815)

106. Dr. D'Angelo also sees variation in the contrast percentages at the various sites for which she provides radiology coverage. (D'Angelo, Vol. 10, p. 1872)

107. Ms. Platt testified that OMLLC's 44,68% contrast percentage did not fit with the contrast experience of other outpatient MRI providers in Health Service Area ("HSA") VI (which includes Onslow County) in that no other provider has that high of a percentage. (Platt Tr., Vol. 8, pp. 1490-91)

108. No evidence was offered at trial showing any existing outpatient facility that has the exact same contrast percentage as a hospital. *See also* page 50 of the Agency File, which shows the procedure mix for hospitals in HSA VI. As shown in the Agency File, the contrast percentages range from 0 to 36.1 in Health Service Area VI, and the average among the outpatient facilities in HSA VI is 22.3%. As is the case with the outpatient facilities, there is significant variation in contrast percentages among the hospitals. It also shows that hospitals tend to have a higher mix of contrast than the freestanding MRI providers in HSA VI. (Jt. Ex. 1, p. 49, 50) (Platt, Vol. 8, p. 1493)

109. Ms. Platt explained that OMLLC would have to have at least 39.4% contrast in order to reach 4,118 weighted MRI procedures in Year 3. (Platt Tr., Vol. 8, p. 1485)

110. Two MRI outpatient centers are especially noteworthy because of their connection to the owners of OMLLC. (Jt. Ex. 1 at 49) Eastern Radiologists, Inc. ("ERI") one of the OMLLC owners, owns two MRI scanners in Greenville at an outpatient center called Greenville MRI. Greenville MRI's contrast experience is 36.1%. The other owner of OMLLC, Coastal, reads MRI scans at an outpatient center in Craven County called Coastal Carolina

Healthcare, P.A. Coastal Carolina's contrast percentage is 26.4%. (Platt Tr., Vol. 8, pp. 1491-92) Thus, the actual experience of the owners at two other outpatient facilities in the same health service area in Eastern North Carolina is not consistent with the projected 44.68% contrast level at OMLLC.

111. In order to have the *exactly the same* outpatient contrast percentage as Onslow Memorial Hospital, OMLLC's patient population would have to be *exactly the same* as OMH's patient population. (Feole Tr., Vol. 8, p. 1333) Dr. Feole testified that this would not be realistic, since an outpatient facility and a hospital are totally different facilities. (Feole Tr., Vol. 8, p. 1332) Dr. D'Angelo acknowledged that the OMLLC contrast percentage might not be the same as OMH's contrast percentage. It is the patient's medical condition that drives the decision to administer contrast. (Feole Tr., Vol. 8, p. 1319)

112. The overall average contrast experience in Onslow County (which is based on JDI's experience and Onslow Memorial Hospital's experience) is 31.6%. (OMLLC Ex. at 103) A 31.6% contrast percentage would not permit OMLLC to reach the performance standard of 4,118 weighted MRI scans in Year 3.

113. The OMLLC Application failed to include sufficient data to demonstrate that the contrast procedures at a free standing diagnostic center are the same percentages as a hospital MRI scanner.

3. <u>CRITERION 4</u>

N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4") requires the following:

> 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.

114. The Agency found the OMLLC Application did not adequately demonstrate that the proposed project was an effective alternative, and was therefore non-conforming with Criterion 4 based upon the Agency's findings of non-conformity under Criteria 1, 3, 5, 6, 7, 8, 18a and 10A N.C.A.C. 14C.2700. (Jt. Ex. 1 at 553) (Alexander Tr., Vol. 11 at 2149-50)

115. Had OMLLC been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 4. Thus, the Agency's finding of non-conformity under Criterion 4 for the OMLLC Application was a derivative of other findings.

116. Therefore, if the Agency erred in its determination that the OMLLC Application was non-conforming with Criteria 1, 3, 5, 6, 7, 8, 18a, and the Agency Rules, the OMLLC Application would be conforming with Criterion 4.

4. **CRITERION 5**

N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5") requires the following:

> 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.

117. Criterion 5 has two components: (1) the applicant must demonstrate the availability of funds for the capital and operating needs of the project and (2) the applicant must demonstrate that the project is financially feasible. (Alexander Tr., Vol. 11 at 2150)

118. The Agency concluded that OMLLC did not adequately demonstrate the availability of funds for the capital and operating needs of the project. (Jt. Ex. 1 at 564)

119. The OMLLC Application projected the total capital cost of the project at $2,521,208.00. (Jt. Ex. 1 at 560) (Jt. Ex. 3 at 102)

120. In the findings, the Agency concluded that OMLLC failed to include the taxes and freight charges as part of OMLLC's capital costs. (Jt. Ex. 1 at 560) While the Agency acknowledged prior to the hearing that OMLLC had included freight charges as part of its capital costs, this did not change the Agency's conclusion that OMLLC did not adequately demonstrate the availability of funds for the capital and operating needs of the project. (Alexander Tr., Vol. 11 at 2150-51)

121. An applicant must include all costs associated with its project. This includes sales tax. OMLLC was required to pay sales tax and this amount should have been included in the OMLLC Application.

122. The Agency calculated the tax omitted from the OMLLC Application by using 6.5%. Based on the Agency's calculation, the omitted sales tax totaled $129,786.00. (Jt. Ex. at 561) When the Agency added the projected sales tax to the capital cost projected by OMLLC, the capital cost of the project totaled $2,654,936.00. Therefore, the Agency concluded that $2,521,208.00 capital costs projected by OMLLC in the Pro Forma were not reasonable or reliable. (Jt. Ex. at 562)

123. David Meyer, OMLLC's expert, admitted that he failed to include the sales tax for the cost of the MRI scanner and the contrast injector in the OMLLC capital cost form when he prepared the application. Mr. Meyer agreed that the OMLLC Application should have included 6.75% sales tax totaling $138,534.00 based on the purchase price of the MRI scanner and the contrast injector stated in the vendor quote provided by Siemens and included in the OMLLC Application. (Meyer Tr., Vol. 3, pp. 434-37)

124. The project was proposed to be financed entirely with bank loans from First Citizens Bank. OMLLC provided three funding letters from First Citizen's Bank with their

Application. Each of the three funding letters included the loan amount, the purpose of the loan and a forecast of the terms of the loan. One of the funding letters provided by OMLLC was a loan of $2,052,352,00 to cover the cost of the machine, and one was a loan of $383,200.00 to cover the cost of leasehold improvements. Thus the total funding to be provided for the capital costs of $2,435,552.00 did not exceed the $2,654,936.00 total capital costs of the projected project. (Alexander Tr., Vol. 11, pp. 2151-52) (Jt. Ex. 1, pp. 562-64)

125. William P. Franklin, Jr. of First Citizens Bank testified that the bank's legal counsel drafted the funding letter, and relied on information from the borrower about the amount of money needed. The letter says nothing about loaning more money to anyone. (Franklin, Vol. 7, p. 1196)

126. Ms. Alexander testified that because OMLLC was short of funds necessary to cover capital, the Agency looked at the total funds available to determine if there was adequate funding available to cover the projected cost capital cost and working capital of the project. The OMLLC Application projected start-up and working capital cost of $150,000.00, and provided a funding source for $250,000.00. While this difference left an extra $100,000.00 available to OMLLC, it was not adequate to make up the difference between the $2,654,936.00 capital cost of the projected project and the $2,435,552.00 funding available for capital cost. (Alexander Tr., Vol. 11, pp. 2151-52) (Jt. Ex. 1, pp. 562-64)

127. The OMLLC Application contained no documentation which indicated a funding source for the capital cost shortfall. The applicant OMLLC was the only entity to provide a certification page for the application. The ultimate parent entities of OMLLC, Eastern Radiologists, Inc. and Coastal Radiology, PLLC, elected not to include any information

concerning their financial positions, and no audited financial statements for any entity were included with the application. (Alexander Tr., Vol. 11, p. 2155)

128. The omission of sales tax was not a "change in a project" that implicated the cost overrun provisions of N.C. Gen. Stat. 131E-176(16) that allow an applicant to spend up to 115% of its approved capital before another CON is required. (Carter, Vol. 11, p. 2013)

129. OMLLC contends that the Agency should have "conditioned" the application to provide the missing documentation of funding for the sales tax. Mr. Meyer acknowledged that the decision to condition an applicant to provide missing information is discretionary with the Agency. (Meyer Tr., Vol. 3, p. 509) Ms. Alexander explained that the Agency does not condition an applicant to provide missing documentation of funding for sales tax unless the applicant is conforming to all other criteria. Furthermore, in the case of a competitive review, the applicant must be the approved applicant before the Agency will condition the applicant.

130. In the instant case, both Ms. Alexander and Ms. Thorne-Williams testified that they did not consider whether the OMLLC Application could be conditioned on the issue of omitting capital costs in the form of sales tax related to the purchase of the MRI, because they had already determined that the Application was non-conforming with Criterion 3. See Thorne-Williams, Tr. pp. 689-98; Alexander, Tr. pp. 2150-53, 2274-77.

131. The testimony and other evidence offered at the hearing did, however, indicate that the omission of a capital cost, standing alone could be conditioned by the Agency. See Meyer, Tr. pp. 326-332; Thorne-Williams, Tr. p. 690; Carter, Tr. pp. 2017-18; Alexander, Tr. pp. 2150-53, 2274-77. Also see generally, e.g., JDI Ex. 7, 9-10, 15, 18-19, 21, 26-28, 46, 48, and 50-53; OMLLC Ex. 135-138; 142; and 144.

132. Ultimately, Mr. Carter and Mr. Meyer concluded that the Agency, within its discretion, should have found the OMLLC Application conditionally conforming with the requirement that the applicant document the availability of funds under Criterion 5. See Carter, Tr. pp. 1962-67, 2017-18; OMLLC Ex. 144, pp. 4-5. See Meyer, Tr. pp. 327-32, 502. There certainly is no prohibition preventing the Agency from conditioning the OMLLC Application on this issue, so long as it was otherwise conforming.

133. There was no evidence produced at trial showing that the Agency abused its discretion by not conditioning OMLLC to provide the missing documentation regarding the sales tax. In fact, the findings upon which OMLLC relied are distinguishable from the present situation:

- **Health Service Area II 2004 PET Scanner Review (JDI Exhibit 21):** This application was not missing any capital costs. There was a typographical error in the High Point Regional Health System CFO letter. The CFO letter committed funding for $2,947,171 and the Section VIII capital cost form said the project would cost $2,967,171, so there was a one digit difference, amounting to $20,000 difference, between the two documents. High Point Regional proposed to fund the project from its reserves and included a copy of its audited financial statements in the application, which demonstrated it had ample funds for the project. *See* Exhibit 21, page 16. High Point was conditioned to provide the Agency with a letter from the CFO committing sufficient funds for the capital and working capital needs of the project. *See* Exhibit 21, page 17.

- **NCBH Outpatient Imaging, LLC (OMLLC Exhibit 135):** This application was not missing any capital costs. Rather, the issue was that North Carolina Baptist Hospital and Wake Forest University Health Sciences did not provide funding letters.

- **Presbyterian Hospital Mint Hill, LLC (OMLLC Exhibit 137):** This application was not missing any capital costs. Rather, the applicant proposed two different types of financing: (1) reserves; or (2) bond financing. The Agency requested clarification regarding which entity would be funding the project.

- **Porters Neck Imaging, LLC (OMLLC Exhibit 136):** Porters Neck Imaging omitted sales tax from its application, a fact which was pointed out in the comments that Atlantic Orthopedics submitted against the Porters Neck Imaging

application. *See* OMLLC Exhibit 105. However, in its responses to comments, Porters Neck Imaging pointed out that it had an additional $225,170 in reserves to pay for the sales tax. *See* JDI Exhibit 96, page 3. That is not the case here, because OMLLC did not have sufficient additional funds to cover the missing sales tax. Moreover, while Porters Neck Imaging was found conforming under Criterion 5, its application was ultimately disapproved.

134. Independent of the Agency's findings regarding the documentation of the availability of funds necessary to develop the project, the Agency further concluded that the OMLLC Application failed to demonstrate the financial feasibility of the project as proposed under Criterion 5. See Joint Ex. 1, Agency File, pp. 564-65. The Agency Findings cite two separate bases for its finding of non-conformity under this second component of Criterion 5.

135. First the Agency cited the fact that the financial projections were premised upon the need analysis discussed under Criterion 3, which the Agency determined was unreasonable. Thus, given the fact that the assumptions underlying the financial projections were deemed unreasonable, the Agency concluded that OMLLC failed to document the financial feasibility of the facility. See id.

136. Secondly, the Agency cited to what it interpreted to be undocumented operational costs related to staffing under Criterion 7. Thus, the Agency concluded that the projections of operational costs and expenses were unreasonable in that they failed to account for certain future staffing costs. See id.

137. Each of these areas is addressed more fully herein.

138. The Agency witnesses testified that, had OMLLC been found conforming with, in the first instance Criterion 3, and, in the second instance Criterion 7, the Agency would have determined that the OMLLC Application was conforming with the financial feasibility component of Criterion 5. Thus, the Agency's finding of non-conformity under this prong of

Criterion 5 for the OMLLC Application was a derivative of other findings. See Joint Ex. 1, Agency File, pp. 564-65; Thorne-Williams, Tr. pp. 704-05; also see OMLLC Ex. 144, pp. 4-5. Therefore, if the Agency erred in its determination that the OMLLC Application was non-conforming with the Criterion 3 and Criterion 7, the OMLLC Application should have been determined to be conforming with the financial feasibility requirements of Criterion 5.

5. **CRITERION 6**

N.C. Gen. Stat. § 131E-183(a)(6) ("Criterion 6") requires the following:

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

139. The Agency determined that the OMLLC Application proposed "to acquire no more than one fixed MRI scanner and to establish a diagnostic center at a new medical office complex in Onslow County," which was consistent with the need determination in the 2009 SMFP. Joint Ex. 1, Agency File, p. 566; accord Joint Ex. 3, OMLLC App., p. 10; OMLLC Ex. 101, p. 149; Agency Ex. 8, p. 149. The Agency nonetheless concluded that, due to its determination that the OMLLC Application was non-conforming with Criterion 3, the applicant did not demonstrate that the proposed service would not result in an unnecessary duplication of existing MRI services. See id.; Thorne-Williams, Tr. pp. 705-06; Alexander, Tr. pp. 2156-57.

140. Had OMLLC been found conforming with Criterion 3, then the Agency would have determined that the OMLLC Application was conforming with Criterion 6. Thus, the Agency's finding of non-conformity under Criterion 6 for the OMLLC Application was a derivative of other findings. See id.; Thorne-Williams, Tr. pp. 705-06; Alexander, Tr. pp. 2156-57; also see OMLLC Ex. 144, p. 5.

141. Thus, to the extent that the Agency erred in its determination that the OMLLC Application was non-conforming with Criterion 3, the OMLLC Application would be conforming with Criterion 6. See id.

6. CRITERION 7

N.C. Gen. Stat. § 131E-183(a)(7) ("Criterion 7") provides that:

> 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.

142. The Agency noted that the OMLLC Application identified it's projected administrative, clinical, and support staff, as well as operational costs related thereto. See Joint Ex. 1, Agency File, p. 568-69; accord Joint Ex. 3, OMLLC App, pp. 93-95, 126. The Agency further found that OMLLC adequately documented it policies and procedures related to its staff and documented the availability of a proposed medical director. Id.; accord Joint Ex. 2, JDI App, pp. 315-20, 347-62.

143. The OMLLC Application proposed that the new OMLLC facility would be managed by Eastern Radiologists (hereinafter "ERI") which was a parent company / owner of the applicant entity, OMLLC. See Joint Ex. 3, OMLLC App, pp. 12, 93-95, 126, 176-97; Meyer, Tr. pp. 310-18; McLaughlin, Tr. pp. 453-61. In return for providing management services, ERI would be paid a management fee, which was included in the operational costs for the facility in the financial proformas. See Joint Ex. 3, OMLLC App, pp. 12, 93-95, 126, 176-97; also see Meyer, Tr. pp. 310-18.

144. This management relationship was to be governed by the provisions of a management agreement which would be executed at some point in the future. See Meyer, Tr. pp. 310-18; McLaughlin, Tr. pp. 453-61. OMLLC provided an unexecuted and incomplete draft

version of the agreement as Exhibit 4 to the Application. See Joint Ex. 3, OMLLC App, pp. 176-97; Meyer, Tr. pp. 310-18; McLaughlin, Tr. pp. 453-61;

145. The Agency witnesses were aware that the draft management agreement was incomplete and had not been executed. See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69. Both Ms. Alexander and Ms. Thorne-Williams admit that it was not uncommon for applicants to provide unexecuted draft versions of such agreements in applications. Id. Based on the CON law's prohibition on incurring financial obligations related to the development of a CON-regulated service prior to the issuance of a CON, they further acknowledged that OMLLC was barred from executing a final version of the management agreement prior to the approval of the OMLLC Application by the CON Section. See Thorne Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69; compare and accord N.C. Gen. Stat. §§ 131E-176(7) and (16).

146. The Agency, however, concluded that the draft management agreement provided by OMLLC was not consistent with the narrative discussion of staffing found in the body of the application. See Joint Ex. 1, Agency File, p. 568-69; Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69; compare Joint Ex. 3, OMLLC App, pp. 12, 93-95, 176-97.

147. Both Ms. Thorne-Williams and Alexander were aware of the representations in the narrative portions of the OMLLC Application indicating that all costs associated with the operations manager were to be paid by ERI as part of the management agreement. See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69; compare Joint Ex. 3, OMLLC App, pp. 12, 93-95. Yet, both interpreted the language found in the draft management agreement as being inconsistent with the narrative. See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69.

148. In particular, both Ms. Alexander and Ms. Thorne-Williams concluded that the OMLLC Application failed to document the costs associated with the operations manager.

149. Both Ms. Alexander and Ms. Thorne-Williams admitted that the draft management agreement was ambiguous on certain issues, omitted terms, and lacked an Exhibit D, as referenced in Exhibit B, to the agreement. See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2258-69; accord Joint Ex. 3, OMLLC App, pp. 176-97. Ms. Alexander also acknowledged that, since there was no Exhibit D to the draft management agreement, there were no specifically identified costs that would be passed-through to the OMLLC facility. See Alexander, Tr. pp. 2258-69.

150. The narrative of the application, however, specifically stated on page 93:

> *OMLLC will have a management agreement with ERI, which will provide administrative oversight (Operations Manager) for the proposed facility. The Operations Manager salary is included in the Management fee shown in the proforma financial statements.*

Joint Ex. 3, OMLLC App, p. 93.

151. The OMLLC Application further provided a chart reciting all of the projected staffing for the facility on page 94. A note to that chart stated:

> *Note: Operations Manager salary paid by ERI, as per the Management Agreement. Therefore, the salary is included in the management fee shown in the proforma financial statements in Section XIII.*

Joint Ex. 3, OMLLC App, p. 94.

152. As represented in each of the above-quoted statements, the financial proformas included in the OMLLC Application contained a line-item for the management fee payable to ERI. See Joint Ex. 3, OMLLC App., p. 126; compare, Meyer, Tr. pp. 310-18.

153. Michael McLaughlin, M.D., as the president of ERI, would be the person with authority to execute a final version of the management agreement. He stated that it was the

intention of ERI to provide the operations manager as a non-pass-through cost, and one which was covered by the based management fee provided under the draft agreement. See McLaughlin, Tr. pp. 453-61.

154. Dr. McLaughlin explained that this is the arrangement that ERI has used at other facilities which they manage. The reason for this is due to the fact that there is no need for a fulltime operations manager, and it was intended that a single individual would serve as a shared operations manager for multiple facilities under ERI's management. This shared operations manager would be compensated by ERI and would be allocated as a fractional full-time equivalent (hereinafter "FTE") for each of the facilities which were managed. See McLaughlin, Tr. pp. 453-61.

155. Dr. McLaughlin signed the letter of intent for the OMLLC Application, as well as a check from ERI for half of the CON application filing fee. This is some indicia of ERI's intent to comply with the representations in the OMLLC Application, including that the operations manager's expense would be paid by ERI. See Joint Ex. 1, Agency File, pp. 16-17; Alexander, Tr. pp. 2260-61.

156. Walter Lindstrand, the COO for ERI, testified that the draft version of the agreement which was included in the OMLLC Application was little more than a template, which had previously been used by ERI for other facilities, and lacked the final language which would apply to the management of the OMLLC Facility. See Lindstrand, Tr. pp. 1151-53.

157. While Ms. Alexander viewed the draft management agreement as being inconsistent with the narrative discussion regarding the operations manager, the draft agreement did not expressly contradict the narrative. See Alexander, Tr. pp. 2260-61.

158. Ms. Thorne-Williams agreed that while the representations in the draft management agreement as to who would pay for the cost of the operations manager were ambiguous, the representation in the body of the application that this cost would be paid by the management company, was not ambiguous. Thorne-Williams, Tr. pp. 709-20.

159. Both Ms. Alexander and Ms. Thorne-Williams agreed that if the OMLLC Application was otherwise conforming with all other Statutory Review Criteria, then the deficiencies cited under Criterion 7 could have been conditioned. See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2260-61.

7. **CRITERION 8**

N.C. Gen Stat.§ 131E-183(a)(8) ("Criterion 8") provides that:

> 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.

160. In concluding that the OMLLC application was nonconforming to Criterion 8, the Agency again pointed to purported inconsistencies between the draft management agreement attached to the OMLLC Application as Exhibit 4 and the affirmative representations in the application narrative and financial proformas with regard to ancillary and support services. Joint Ex. 1, Agency File, pp. 570-71.

161. In addition to these findings, the Agency also concluded that it was unclear whether housekeeping and purchasing services would be provided at the OMLLC facility. Id.

162. Both Ms. Alexander and Thorne-Williams acknowledge that the financial proformas for the OMLLC Application did include an operational cost line-item for "Housekeeping / Laundry." See See Thorne-Williams, Tr. pp. 709-20; Alexander, Tr. pp. 2260-61; accord Joint Ex. 3, OMLLC App., p. 126.

163. David Meyer testified that all housekeeping and laundry costs were included in the line-item tied to those services in the financial proformas and that, in his experience, the Agency had not required more documentation of such services in prior decisions. See Meyer, Tr. pp. 310-18.

164. Ms. Alexander testified that while there was a line-item cost identified for housekeeping and laundry services, there was no documentation in the application regarding who would be providing these services. See Alexander, Tr. pp. 2260. In particular, Ms. Alexander testified that documentation of the service agreements or contracts for such services should have been included in the application. See Alexander, Tr. pp. 2260-61.

165. Ms. Alexander could not, however, cite to any prior findings where the Agency had required additional documentation of the provider of housekeeping and laundry services. See Alexander, Tr. pp. 2260-61. Just as with the housekeeping and laundry services, the OMLLC Application financial proformas contained no documentation related to other service providers, but the Agency did not find that the documentation for these services was lacking, despite the fact that the costs allocated for those services far exceeded those allocated for laundry and housekeeping services. See Alexander, Tr. pp. 2260-61; compare Joint Ex. 3, OMLLC App., p. 126.

166. The Agency Findings related to the provision of housekeeping and laundry services, did not cite a failure to provide contracts or agreements related to the provision of laundry and housekeeping services as related by Ms. Alexander, but rather included a single sentence stating that it was unclear under the draft management agreement whether housekeeping services would be provided by the management company. Joint Ex. 1, Agency File, p. 571.

167. On the issue of purchasing services, Mr. Meyer testified that there was no need for a dedicated staff member for purchasing of equipment. He testified that all purchasing responsibilities would be the responsibility of the staff members constituting the 2.4 FTEs allocated to "Registration / Receptionist" positions, which were described in a job description included in as part of Exhibit 10 to the OMLLC Application. See Meyer, Tr. pp. 310-18; Joint Ex. 3, OMLLC App., pp. 93-94, 361-62. The costs for these support staff personnel were accounted for in the financial proformas under the "Support Personnel" line-item in the financial proformas. See Meyer, Tr. pp. 310-18; Joint Ex. 3, OMLLC App., pp. 93-94; 126.

168. Ms. Alexander also admitted that there is no Agency requirement that an application's proformas include a specific line item for staff to perform purchasing.. Alexander, Tr. pp. 2260-61.

169. In contradiction to the Agency's conclusion under Criterion 8, the Agency Findings found that the OMLLC Application was conforming with the Agency Rules regarding support services and staffing, codified at 10A N.C.A.C. 14C .2704 and 10A N.C.A.C. 14C .2705. See Joint Ex. 1, Agency File, pp. 603-07. Mr. Meyer testified that the point of these regulations was to assess the adequacy of the staffing and support services documented in the application and that, without more, a finding of conformity with these rules should result in a finding of conformity under Criterion 8. See Meyer, Tr. pp. 310-18. Ms. Thorne-Williams could not cite a reason for distinguishing between the requirements of the Agency Rules and those of Criterion 8. Thorne-Williams, Tr. pp. 709-20.

170. Ultimately, the Agency admitted that, were the OMLLC Application otherwise conforming with all other Statutory Review Criteria, then the deficiencies cited under Criterion 8 could have been conditioned. See Thorne-Williams, Tr. pp. 730-31.

8. **CRITERION 12**

171. Criteria 12 requires the applicant to adequately demonstrate that the cost, design and means of construction represent the most reasonable alternative and that the construction will not unduly increase the charges of providing health services. (Jt. Ex. 1 at 572)

172. OMLLC proposed to lease 4,000 square foot space in a new medical complex for the proposed diagnostic center. The applicant estimated the cost of construction at $630.00 per square foot. Cost would include the shell and up-fit costs associated with operating a new MRI scanner. (Jt. Ex. 1, pp. 572-73) (Jt. Ex. 3, pp. 119)

173. The Agency properly concluded that OMLLC adequately demonstrated that the cost, design and means of construction represent the most reasonable alternative and that the construction will not unduly increase the charges of providing health services. (Jt. Ex. 1 at 573).

9. **CRITERION 13c**

N.C. Gen. Stat. § 131E-183(a)(13)(c) (hereinafter "Criterion 13(c)") provides as follows:

> *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:*
>
> > *(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;*

Joint Ex. 1, Agency File, pp. 574, 577.

174. Criterion 13c requires an applicant to show that the elderly and the medically underserved groups 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. (Jt. Ex. 1 at 577)

175. The Agency properly concluded that the OMLLC Application was conforming with Criterion 13(c), and adequately demonstrated that medically underserved groups would have access to the proposed services to be offered at the OMLLC facility. Joint Ex. 1, Agency File, pp. 579-80.

176. Ms. Alexander testified that OMLLC documented its willingness to serve all patients, regardless of their ability to pay. See Alexander, Tr. pp. 2169-70, ; Joint Ex. 1, Agency File, pp. 580-81; compare Joint Ex. 3, OMLLC App., p. 82. Ms Alexander further testified that the payor mix proposed in the OMLLC Application—which was based upon the experience of Coastal Radiology serving outpatient MRI patients at Onslow Memorial Hospital—was reasonable given that OMLLC was to be a new provider and had no way of knowing what the actual payor mix would be. See Alexander, Tr. pp. 2169-70; Joint Ex. 1, Agency File, pp. 580-81; compare Joint Ex. 3, OMLLC App., pp. 90-91, 127-28.

177. At hearing, JDI asserted that the OMLLC payor mix was based upon unreliable data and was unreasonable. In particular, Kathy Platt, who prepared the JDI Application, testified that the payor mix was incorrect due to data found in a printout of charge data for Coastal Radiology, which was produced by OMLLC during discovery. See Platt, Tr.; JDI Ex. 36, pp. 1-4.

178. Based upon that data found in JDI Ex. 36, Ms. Platt asserted that the actual Medicare and Medicaid percentages served by Coastal Radiology were lower than those stated in the OMLLC Application. Id.

179. Dr. Everett, the managing member of Coastal Radiology, testified that the data found in JDI Ex. 36, was incomplete and only covered a period spanning from August 2008 through January 2009. See Everett, Tr. pp. 1802-07; accord JDI Ex. 36, pp. 1-4. Coastal Radiology changed billing services providers and as a result, all charge and billing data prior to that time period had been corrupted and was no longer accessible in any form other than prior printed and voluminous reports. Id.

180. Dr. Everett pointed out that the volume of elective procedures covered by insurance typically increase during the last half of the calendar year due to the fact that the insurance deductibles applicable to patients have been exceeded. Id. Dr. Everett further testified that it was unclear whether the data in JDI Ex. 36 included charity care performed by Coastal Radiology, since such care is typically never billed. Id.

181. As a result, the data found in JDI Ex. 36 reflects an incomplete picture of the overall payor mix for outpatient procedures performed on the MRI at Onslow Memorial Hospital and read by Coastal Radiology. Id.

182. Dr. Everett stated that, due to the loss of Coastal Radiology's historical charge data, the best proxy for the practice's payor mix would be the outpatient payor mix for Onslow Memorial Hospital as an MRI provider, since Coastal Radiology read all scans performed on the Onslow Memorial Hospital MRI and the outpatient payor mix of the two should essentially be the same. Id.

183. Elizabeth D'Angelo, M.D., Chair of the Radiology Department at Onslow Memorial Hospital, member of Coastal Radiology, and proposed medical director for the OMLLC facility, mirrored these opinions and cited the outpatient MRI scan experience of

Onslow Memorial Hospital as being the same as the experience of Coastal Radiology. See D'Angelo, Tr. pp. 1847, 1904.

184. Thus, the probative value of JDI Ex. 36 on the issue of payor mix is marginal, at most, while the testimony of Ms. Alexander, paired with that of Doctors Everett and D'Angelo, is both reliable and trustworthy and is based upon the firsthand experience of each witness.

185. Furthermore, the conclusions drawn by Ms. Platt during her testimony, while not unreliable *per se*, were based upon incomplete data which are unreliable for the purposes stated by Ms. Platt.

186. OMLLC's Application adequately demonstrated that the elderly and the medically underserved groups 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 the Agency correctly and reasonably determined that the OMLLC Application conformed to Criterion 13(c).

10. CRITERION 13d

187. Criterion 13d requires an applicant to offer a range of means by which a person will have access to its services. (Jt. Ex. 1 at 580)

188. The Agency properly noted that the OMLLC Application demonstrated that patients would have access to the proposed services by physician referrals, and concluded that the OMLLC Application was conforming to Criterion 13d. (Jt. Ex. 1 at 581)

11. CRITERION 14

189. Criterion 14 requires an applicant to demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable. (Jt. Ex. 1 at 581)

190. The Agency noted that the OMLLC Application expressed willingness to accommodate student training programs, and included copies of existing clinical agreements between ERI and local community colleges. (Jt. Ex. 1 at 582)

191. The Agency properly concluded that the applicant demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area, and determined that the OMLLC Application was conforming to Criterion 14. (Jt. Ex. 1 at 582)

12. **CRITERION 18a**

N.C. Gen. Stat. § 131E-183(a)(18a) ("Criterion 18a") requires the following:

> 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.

192. The Agency determined that, due to its determination that the OMLLC Application was non-conforming with Criteria 1, 3, 4, 5, 6, 7, and 8 as well as the Agency Rules, the applicant did not demonstrate that the proposed service "would have a positive impact upon the cost effectiveness, quality, and access to the proposed services." Joint Ex. 1, Agency File, p. 583.

193. Had OMLLC been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 18a. Thus, the Agency's finding of non-conformity under Criterion 18a for the OMLLC Application was a derivative of other findings. <u>See</u> <u>id.</u>; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; <u>also</u> <u>see</u> OMLLC Ex. 144, p. 5.

194. Therefore, if the Agency erred in its determination that the OMLLC Application was non-conforming with Criteria 1, 3, 4, 5, 6, 7, and 8, as well as the Agency Rules, the OMLLC Application should have been determined to be conforming with Criterion 18a.

B. REGULATORY REVIEW CRITERIA

195. The rules contained in 10A N.C.A.C. 14C.2700, *et seq.*, contain criteria and standards for any CON application proposing MRI services. These rules were applicable to the OMLLC Application since the application proposed to develop a new diagnostic facility with one fixed MRI. (Jt. Ex. 1, pp. 600-07) (Alexander Tr., Vol. 11, p. 2174)

10A N.C.A.C. 14C .2703(b)(3)

10A N.C.A.C. 14C.2703(b)(3) provides in pertinent part that:

> (b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner. . . shall:
>
> . . .
>
> (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:
>
> ...
>
> (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,...

196. At the time of the Agency's review, there were two existing fixed MRI scanners in Onslow County; one of these was operated by Onslow Memorial Hospital and the other by JDI at its existing facility in Jacksonville, North Carolina. See OMLLC Ex. 101, p. 149; Agency Ex. 8, p. 149; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72. Therefore, the

performance standard applicable to the applicants in this review required that they project at least 4,118 weighted scans on the proposed MRI scanner by the end of the third year of operation. See id.

197. OMLLC projected to perform 4,193 weighted procedures during in third year of operations following the completion of the proposed project. See Joint Ex. 1, Agency File, pp. 599-600; accord Joint Ex. 3, OMLLC App, p. 35. This number of scans exceeded the number required by the performance standards.

198. Due to its finding that OMLLC failed to adequately document the reasonableness of its projected volumes and utilization under Criterion 3, the Agency determined that the OMLLC Application was non-conforming with 10A N.C.A.C. 14C .2703(b)(3).

199. Had OMLLC been found conforming with Criterion 3, then the Agency would have determined that the OMLLC Application was conforming with 10A N.C.A.C. 14C .2703(b)(3). Thus, the Agency's finding of non-conformity under 10A N.C.A.C. 14C .2703(b)(3) for the OMLLC Application was a derivative of other findings. See id.; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; also see OMLLC Ex. 144, p. 5.

200. Thus, if the Agency erred in its determination that the OMLLC Application was non-conforming with Criterion 3, the OMLLC Application would be conforming with 10A N.C.A.C. 14C .2703(b)(3). See id.

II. THE JDI APPLICATION

201. The Agency found the JDI Application non-conforming with Criteria 1, 3, 4, 5, 6, 13(c), 18a, and the rules at 10A N.C.A.C. 14C.2702(c)(8), .2702(c)(9) and .2703(b)(3) (Jt. Ex. 1 at 504-607)

A. STATUTORY REVIEW CRITERIA

1. **CRITERION 1**

202. The CON Section's concluded that the JDI Application is consistent with the need determination in the 2009 SMFP because the JDI Application proposed to develop no more than one MRI scanner; however, the Agency concluded that the JDI Application is nonconforming with Policy GEN-3 and therefore is nonconforming with Criterion 1. (Jt. Ex. 1 at 505, 509)

203. Policy GEN-3 requires a CON application to: (1) promote safety and quality; (2) promote equitable access; and (3) maximize healthcare value. (Jt. Ex. 1, p. 505)

204. Notwithstanding the Agency's stipulation prior to the hearing that JDI did include a line item for professional fees in its performance standards (See stipulations 9 and 10 above), the Agency found the JDI Application non-conforming with Criterion 5 based upon its non-conformity with Criterion 3, and, thus, Criterion 1. Therefore, this did not change the Agency's conclusion that JDI failed to demonstrate that its proposed project would maximize healthcare value. (Alexander Tr., Vol. 11, p.2180)

205. The Agency noted in its Findings that the JDI Application stated that the applicant would offer competitive charges and global billing in a cost-effective setting, making it attractive to both patients and payors, and further, outlined the special efforts JDI planned to contain costs of offering the proposed services. (Jt. Ex. 1 at 508)

206. Nevertheless, the Agency found that JDI did not adequately demonstrate the need the population it proposes to serve has for its proposed project under Criterion 3, and also did not demonstrate that the project it proposed is financially feasible under Criterion 5. Consequently, based on the same reasoning, the Agency concluded that the JDI Application was non-conforming with Policy GEN-3 because it did not demonstrate the process by which it planned to

maximize healthcare value. Therefore, the Agency determined that the JDI Application was non-conforming under Criterion 1. (Jt. Ex. 1 at 509)

207. Had JDI been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 1. Thus, the Agency's finding of non-conformity under Criterion 1 for the JDI Application was a derivative of other findings. See id.; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; also see OMLLC Ex. 144, p. 5.

208. Therefore, if the Agency erred in its determination that the JDI Application was non-conforming with Criteria 3 and 5, the JDI Application would be conforming with Criterion 1.

2. **CRITERION 3**

N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3") provides that:

> 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.

209. Criterion 3 of the CON Law contains two parts: (1) the applicant must identify the population it proposes to serve; and (2) it must also demonstrate the need that the population has for the service proposed.

210. The Agency found the JDI Application nonconforming with both prongs of Criterion 3. Specifically, it found that JDI failed to adequately identify the population to be served, and also failed to adequately demonstrate the need this population has for the proposed MRI services. (Jt. Ex. 1, pp. 511-530)

a. **Population Proposed to Be Served**

211. The Agency concluded that JDI failed to identify the population it proposed to serve. JDI is an existing business that has been providing mobile MRI service since 2003 and fixed MRI service since 2006. (Jt. Ex. 2, p. 14) The new scanner would go into the same building as the existing fixed scanner. (Jt. Ex. 2, pp. 7; 15; 127)

212. JDI has a population it serves now and that it will continue to serve if approved for the second scanner. (Jt. Ex. 2, pp. 77-78)

213. In this Review, JDI proposed to serve a population that was broader than Onslow County. JDI proposed to serve a patient population from a primary service area and a secondary service area. (Jt. Ex. 1, pp. 513-14)

214. Ms. Alexander testified that an applicant can identify the population it proposes to serve any way it wants to, and that it is common for applicants to designate a primary service area, a secondary service area, and then a miscellaneous group of "Other," which is what JDI did in this application. (Alexander, Vol. 12, pp. 2335-2336)

215. Ms. Alexander stated that it is rare for an applicant to be found non-conforming based on the failure to identify the population it proposes to serve. She could not identify any other findings to support her conclusion that JDI failed to identify the population it proposes to serve. (Alexander, Vol. 12, pp. 2340-2341)

216. The Agency's issue regarding the population JDI proposes to serve centers on what role if any Carteret and Craven counties have in defining the service area and therefore affect the projected numbers. The question primarily arises because JDI lists Onslow, Jones, Pender, Carteret and Craven counties in the body of tables and also lists them alternatively in footnotes to the tables, appearing to list them twice. Specifically, Table 1 in the JDI application lists Onslow, Duplin, Jones, Pender, Carteret and Craven in both the table and in the footnote.

Table 2 of the application also lists Onslow, Duplin, Jones and Pender in both the table and in the footnote.

217. JDI contends this double listing is a "typographical" error whereas the Agency considers it a substantive error. Whether or not the error is "typographical" is a matter of semantics; the question is whether the error is indeed "substantive." One must then look to other indicia to see if this mistake is clarified.

218. Ms. Alexander acknowledged that applications with typographical errors and minor inconsistencies can be approved. (Alexander, Vol. 12, p. 2321)

219. Ms. Alexander admitted that she would expect the majority of patients that JDI serves and would continue to serve would be from Onslow County. (Alexander, Vol. 12, pp. 2351-232)

220. The Agency's own findings also state that Onslow County is the primary service area, and that Duplin, Jones and Pender Counties are the secondary service area. (Jt. Ex. 1, p. 521; *see also* Table 8 on p. 520 of Jt. Ex. 1 (table identifying the "proposed secondary service area" and the mobile MRI providers in Duplin, Jones and Pender Counties).

221. Regarding the existing population that JDI serves, the application clearly states on several pages that JDI currently serves residents of Onslow County, as well as residents of Carteret, Craven, Duplin, Jones and Pender Counties. (Jt. Ex. 2, pp. 22; 35; 61; 75; 77)

222. The Agency had access to the 2009 MRI Inventory Report which provided patient origin data for JDI for Federal Fiscal Year 2008. (Jt. Ex. 1, pp. 165-166)

223. The application also clearly stated in multiple places that if JDI were approved for the second scanner, JDI's primary service area would be Onslow County and its secondary

service area would be Duplin, Jones and Pender Counties. (Jt. Ex. 2, pp. 19; 22; 25; 35; 50; 53; 54 (depicting a service area map); 61; 77; 78)

224. Ms. Alexander knew that Onslow County was JDI's primary service area. (Alexander, Vol. 12, pages 2351 and 2352) She also recognized that it would be reasonable for JDI to project that the majority of its patients would come from Onslow County since JDI was not relocating and was simply proposing to add a scanner to its existing facility in Jacksonville. (Alexander, Vo1, 12, page 2358)

225. If Onslow County were shifted to the "Other" category as would be the case by the erroneous listing in the note to the table, there would be thousands of patients in the "Other" category, instead of hundreds, which had been the case in the past.

226. Ms. Alexander admitted that she knew that JDI's primary service area was Onslow County and that it would not make any sense to put Onslow County in the "Other" category. (Alexander, Vol. 12, pp. 2351-2352).

227. JDI represented that in the past Carteret and Craven Counties had been included in the secondary service area. (Jt. Ex. 2, p. 77)

228. Since two new scanners had been approved and were coming on line in Carteret and Craven Counties, JDI determined it would not be appropriate for JDI to include those counties in the secondary service area. (Jt. Ex. 2, p. 19)

229. Ms. Alexander acknowledged that it was appropriate for JDI to take these changed circumstances into account and that it would have been a problem if JDI had failed to recognize that two new scanners were coming on line in Carteret and Craven Counties. (Alexander, Vol. 12, p. 2353)

230. JDI therefore stated that it "does not expect to serve a significant amount of patients from these counties." The application went on to state "[T]he omission of Carteret and Craven Counties from the proposed service area will not impact CDI's utilization projections for the proposed project." (Jt. Ex. 2, p. 53)

231. Thus, Carteret and Craven were moved from the secondary service area to "Other," which is the category providers use to collectively designate areas from which they will serve relatively few patients as opposed to listing each area independently. (Jt. Ex. 2, p. 78)

232. JDI also stated that it "will serve any patient in need of MRI services regardless of their county of origin." (Jt. Ex. 2, p. 23)

233. Nowhere in the application did JDI state or imply that it would stop serving patients from Carteret and Craven entirely.

234. Ms. Alexander admitted that she would expect some patients from Carteret and Craven to keep using services at JDI. (Alexander, Vol. 12, pp. 2354-2355) Ms. Alexander also admitted that it was not wrong for JDI to include Carteret and Craven in the "Other" category. (Alexander, Vol. 12, pp. 2359-2360) (Emphasis added) Ms. Alexander did not interpret the JDI Application to suggest that JDI would not serve patients from Carteret and Craven. (Alexander, Vol. 12, p. 2373)

235. Comparing JDI's patient origin from 2008 to its proposed patient origin, it is evident that JDI would not lose patients by moving Carteret and Craven from the secondary service area to "Other."

236. The Agency assumed that by "excluding" Carteret and Craven from the secondary service area, JDI would lose 4.8% of its patients. (Jt. Ex. 1, p. 514) As noted, JDI still projected to serve patients from Carteret and Craven shown in the "Other" category.

237. Moreover, as JDI Tables 1 and 2 show, the increase in number of patients from Onslow County alone (1,668 patients is the difference between the Year 1 patient origin and the 2008 patient origin) would more than make up for the 235 Carteret and Craven County patients that JDI saw in 2008.

238. The text of the application as well as the Agency findings themselves are clear about what counties are included in the primary and secondary service areas.

239. The Agency also included in the Agency File the MRI inventory reports, which include patient origin data. (Jt. Ex. 1, pp. 165-166) From this, the Agency could determine JDI's historical patient origin.

240. At trial, Ms. Alexander compared the patient origin from the inventory reports against page 77 of the JDI Application, and found them to be very similar. The differences are attributable to the fact that the inventory reports are based on Federal Fiscal Year (October 1-September 30), while page 77 of the JDI Application is based on a Calendar Year (January 1-December 31). (Alexander, Vol. 12, pp. 2346-2348)

241. At trial, Ms. Alexander also admitted she could discern the population JDI proposed to serve. (Alexander, Vol.11, pp. 2184-2185)

242. The Agency contends that the alleged inconsistency in the population proposed to be served affected JDI's projections because it made the "base" incorrect. (Alexander, Vol. 11, pp. 2181-2182; 2184-2185) This reasoning does not appear in the Agency's Findings.

243. The argument regarding the alleged wrong "base" is discussed below.

b. Need for the Proposed Project

The Agency Findings pointed to four factors cited by JDI as the basis for its need projections for the new proposed fixed MRI:

- *2009 State Medical Facilities Plan (SMFP) Need Determination*
- *Population Trends*
- *Utilization Trends*
- *Service Area Demand*

(Jt. Ex. 1, p. 515) (Jt. Ex. 2, pp. 50-69)

244. Although the Agency acknowledged that it made mistakes in its analysis of the JDI Application under the need prong of Criterion 3, the Agency concluded that the errors did not affect the ultimate conclusion that JDI failed to demonstrate the need for the proposed project. (Alexander Tr., Vol. 12, p. 2211)

245. The Agency found no problem with JDI's presentation concerning the SMFP need analysis, the population trends and the utilization trends; i.e., the problem is with the service area demand analysis.

246. As the stipulations demonstrate, the Agency made several material mistakes in its analysis of the JDI Application under the demonstration of need portion of Criterion 3. The evidence at trial showed that the Agency made more mistakes than those listed in the stipulations.

247. This Tribunal reiterates that in her testimony Ms. Thorne-Williams was oftentimes incapable of explaining her findings or could not remember in order to justify her findings as to both applicants.

248. On pages 515 and 516 of the Agency File, the Agency reproduced portions of JDI's narrative concerning growth in the service area population, more particularly concerning that older age groups utilize MRI services more frequently and because of that fact "the need for the MRI services in the service area is likely to increase at an even greater rate that [sic] that the population for the entire service area." (Jt. Ex. 1, p. 516)

249. On page 517 of the Agency File, the Agency reproduced JDI's population tables, Tables 4 and 5, segmented by age groups. (Jt. Ex. 1, p. 517) As reflected in Table 5, the service area population is projected to grow by 5%. The greatest growth is projected in the 65+ age range. (Jt. Ex. p. 517)

250. In the findings, the Agency did not criticize JDI's statements about the 65 and over population. Ms. Alexander acknowledged that persons aged 65 and over tend to use health care services, including MRI, more than younger populations. (Alexander, Vol. 12, p. 2384)

251. At trial, Ms. Alexander stated that JDI failed to show a "connection" between the growth in the 65 and over population and the need for the project. (Alexander, Vol. 12, pp. 2384-2385) This reasoning does not appear in the Agency's findings with respect to JDI.

252. The Agency's first error under the need portion of Criterion 3 appears in Table 6 on page 519 of the Agency File. (Jt. Ex. 1, p. 519) The Agency stipulated to this mistake. *See* Stipulation 1.

253. In Table 6, which is entitled "CDI Service Area Historical MRI Use Rate Trends," the Agency purported to do a recalculation of the Compound Annual Growth Rate (CAGR) for total MRI scans in the service area. (Jt. Ex. 1, p. 519)

254. The Agency's recalculation of 12.16% was a mistake because it was based on the wrong number of total MRI scans in the service area for 2004. The correct number for 2004 was 12,487, not 12,847 as the Agency stated in Table 6 (a "typographical" error in juxtaposing two numbers). (Jt. Ex. 1, p. 518). JDI had in its application the correct CAGR for total MRI scans in the service area, 13.76%. (Jt. Ex. 1, p. 62)

255. Each mistake in an analysis is important in that it affects the ultimate conclusion. This mistake is significant, at least in part, because it shows that from the beginning of the

analysis, the Agency was proceeding under the faulty premise that JDI had overstated its volume projections.

256. On page 520 of the Agency File, the Agency created its own table, Table 7, which shows JDI's historical growth. JDI was experiencing double-digit growth and was already performing well over the performance standard of 4,118 weighted MRI scans. *See, e.g.*, 10A NCAC 14C.2703(b)(3).

257. At trial, Ms. Alexander testified that JDI was already well over the 4,118 weighted scans performance standard and that JDI was using its mobile scanner because of volume demands. (Alexander, Vol. 12, p. 2329)

258. Page 520 of the Agency File also contains another Agency-created table, Table 8, entitled "Proposed Secondary Service Area Unweighted MRI Procedures FY2007-FY2009" which shows the growth in the secondary service area.

259. This table is significant for two reasons: first, its title shows that the Agency was aware of the population JDI proposed to serve in its secondary service area; and second, it exposes a mistake that the Agency made on the next page of the Findings, page 521.

260. On page 521 of the Agency File, the Agency states with reference to Table 8: "[f]urther, as illustrated above, the providers of mobile MRI services in the proposed secondary service areas of Duplin, Pender and Jones County show an overall decrease of weighted MRI procedures of -0.82 CAGR from FY2006 through FY2008." (Jt. Ex. 1, p. 521)

261. This statement is wrong. The Agency's own Table 8 shows, the weighted MRI procedures in the secondary service area from FY2006 through FY2008 *increased* by 1.13% CAGR.

262. The Agency asserts that the applicant "switched" between Calendar Years and Fiscal Years on page 522 of the Agency File. The Agency attempts to "correct" JDI's data to make the timeframes consistent. Ms. Platt disagreed that these "corrections" were necessary in that the timeframes used best represented the time since the addition of the fixed MRI at JDI and shows the increase in utilization that occurred after that MRI unit came online, and it was the data available for the most current time period. (Platt, Vol. 8, p. 1416)

263. Even after making these "corrections," the Agency concluded that JDI's annual growth rate increased by 17.01% from 2007 to 2008. (Jt. Ex. 1, p. 522)

264. On pages 523 and 524 of the Agency File, the Agency created Tables 10 and Table 11. (Jt. Ex. 1, pp. 523-524) The purpose of these tables was to show that the percentage of patients JDI served from Onslow County went down between 2007 and 2008, and that JDI would "lose" about 5% of its historical patient origin because Carteret and Craven Counties were moved from the secondary service area to the "Other" category. The Agency stipulates that it reached the wrong conclusion because Table 10 contains mistakes. *See* Stipulation 2:

265. A correct comparison shows that the number of patients in every county in the primary and secondary service areas *increased* between 2007 and 2008. This is significant because it supports the double-digit growth that JDI has experienced in the last several years and JDI's need for a second MRI scanner.

266. JDI Exhibit 34, p. 1950 of the JDI application, contains a chart showing patient origin analysis for JDI which measures the percentage increase in JDI's patient origin from 2007 to 2008:

267. This table shows a significant percentage increase in the number of Onslow residents whom JDI served from 2007 to 2008. In addition, each county in the secondary service

area of Duplin, Jones and Pender Counties experienced a percentage increase. Overall, the percentage increase in patients served by JDI increased 14.77% from 2007 to 2008.

268. On page 524 of the Agency File, the Agency made several other errors in the text immediately following the Agency's Table 11. The first error is the statement "[t]his indicates a 1.8% decrease in those Onslow County patients who received MRI procedures at CDI in fiscal year 2008." The number of Onslow residents served actually increased.

269. Next, the Agency stated "[h]owever, CDI states it does not project patients from those two counties [Carteret and Craven] during it [sic] first three years of operations following completion of the proposed project. CDI does not provide an explanation as to how it plans to compensate for approximately 5% of its utilization with the exclusion of Carteret and Craven Counties." (Jt. Ex. 1, p. 524)

270. This statement is also incorrect in that no where in JDI's application does it state that it would no longer serve patients from Carteret and Craven Counties or that it would "exclude" patients from these counties. (Alexander, Vol. 12, pp. 2374-2376)

271. JDI moved Carteret and Craven counties from the secondary service area to the "Other" category and provided a number and a percentage of patients it projected to serve from the "Other" category. (Jt. Ex. 2, pp. 77-78)(Ex. 12 and 13)

272. Merely excluding counties from a service area is not the same as excluding service to patients from that service area. JDI will serve any clinically appropriate patient with a physician's order for an MRI scan, regardless of where the patient resides. (Jt. Ex. 2, p. 23)

273. Ms. Alexander admitted that she would expect patients from Carteret and Craven Counties to keep using the services at JDI. (Alexander, Vol. 12, pp. 2354-2355)

274. To determine whether the move of Carteret and Craven Counties to the "Other" category was significant, the Agency could have compared just the growth in Onslow residents from 2008 to the first project year (July 1, 2010) to see that the reassignment of Carteret and Craven to the "Other" category was immaterial.

275. In fact, the Agency's own Tables 1 and 2 on pages 513 and 514 of the Agency File reproduce Exhibits 12 and 13. These tables show that the number of Onslow residents which JDI will serve is projected to grow by 1,668 patients, which more than compensates for the 181 residents of Carteret and Craven that JDI served in 2008.

276. On page 524, the Agency states that "[f]urthermore, the patient origin percentage from the secondary service areas of Duplin, Jones and Pender Counties also decreased in fiscal year 2008. In fiscal year 2007, Duplin, Jones and Pender County residents accounted for 8.0% of CDI's patient population; however, in 2008 that percentage decreased to 7.1%." (Jt. Ex. 1, p. 524)

277. The Agency's math is incorrect. In fiscal year 2007, residents of Duplin, Jones and Pender Counties accounted for 7.4% of JDI's patient population. The decrease in percentages was -.3%. While the percentage difference has some significance, it is not as important as the fact that the actual total number of patients from these counties increased from 248 in 2007 to 269 in 2008 since ultimately it must be shown that the applicant meets the milestone number of 4118 weighted scans. *See* Tables that accompany Stipulation 2.

278. On page 525 of the Agency Findings, the Agency criticizes JDI for using "two different sets of population data." (Jt. Ex. 1, p. 525) While it is correct that on page 67, Exhibit 10 of the application, JDI stated that the 2009 population of the service area was 289,816, and

that on page 56, Exhibit 3, JDI stated that the 2009 population of the service area was 292,013, the difference was only 2,197 or 0.7%.

279. It is significant that JDI used the lower number of 289,816 to do its projections. (Jt. Ex. 2, p. 67)

280. Had JDI used the higher population figure of 292,013, it could have achieved the same volume with slightly lower market share percentages. (JDI Ex. 34, p. 1952; Platt, Vol. 8, pp. 1443-1444) Using the lower population figure was a more conservative approach. (Platt, Vol. 8, pp. 1443-1444) *See also* Alexander, Vol. 13, p. 2401

281. Table 12 on page 525 of the Agency File reproduces Exhibit 10 on page 67 of the JDI application.

282. Ms. Platt, JDI's expert witness on CON preparation and analysis, testified that she "interpolated" the 2009 population figure of 289,816 on Table 12. (Platt, Vol. 10, p. 1739) Interpolation is a mathematical exercise wherein she calculated the growth of intervening years by looking at the growth rate of the two starting endpoints.

283. Ms. Platt explained that she interpolated the 2009 figure for simplicity's sake, and it only affected the 2009 population figure on page 67 of the JDI Application. (Platt, Vol. 10, p. 1739)

284. The population figures for 2010, 2011 and 2012 as reflected on Table 12, page 525 of the Agency File, all come directly from the North Carolina Office of State Budget and Management which is identified in the note to the chart. Therefore those numbers are not interpolated. (Platt, Vol. 10, pp. 1739; 1751-1753)

285. Since this information is publicly available, Ms. Platt did not attach print outs of the population data. (Platt, Vol. 10, p. 1753) There is no requirement that the applicant reproduces the population data and includes it in the application. (Alexander, Vol. 13, p. 2405)

286. Ms. Alexander incorrectly believed all of the population figures for 2009-2012 were interpolated. (Alexander, Vol. 12, p. 2391)

287. On page 526 of the Agency File, the Agency stated that "[h]owever, the applicant failed to provide any assumptions or methodology to demonstrate that it is reasonable for CDI to serve 5,842 residents of Onslow County [6,519 (CDI procedures PY1) x 89.6 Onslow County) = 5,842] in PY1 when only 5,877 residents of Onslow County had MRI scans performed any where [sic] in Onslow County in FY 2008." (Jt. Ex. 1, p. 526)

288. As Ms. Platt explained, this statement was erroneous because it failed to recognize the number of patients that are also out-migrating from the service area from Onslow County. (Platt, Vol. 8, p. 1425)

289. The year 2006 is the last year for which reliable patient origin data from the DHSR Medical Facilities Planning Section is available. MRI patient origin data for 2006 shows that a total of 9,812 Onslow County residents had MRI scans. Only 7,067 of these scans were performed in Onslow County, meaning 2,745 Onslow County residents received MRI's outside of the county. Several hundred Onslow residents had MRI scans in New Hanover, Craven, Pitt, Carteret, Durham and Orange Counties. (Jt. Ex. 1, p. 196)

290. This is data that the Agency had available to it and is included in the Agency File. (Jt. Ex. 1, p. 196)

291. Thus, the pool of patients available for JDI to serve is significantly larger than the 5,877 Onslow residents identified by the Agency on page 526 of the Agency File. (Platt, Vol. 8, p. 1425)

292. Through the addition of a second scanner in Onslow County, it is reasonable to expect that fewer patients from Onslow County would leave Onslow County (out-migrate) to have MRI scans elsewhere. (Platt, Vol. 9, p. 1541) Dr. D'Angelo agrees that people leave Onslow County for MRI scans. (D'Angelo, Vol. 10, p. 1911)

293. The Agency stipulates that the Agency File on page 526 erroneously states "In FY2008 CDI served 2,614 Onslow County residents. Thus, in PY1, the applicants are projecting a 223% increase in Onslow County residents who are projected to have scans performed at CDI." *See* Stipulation 3:

294. On page 526 of the Agency File, the Agency created Table 13 which shows average annual growth rates in MRI scans for MRI providers in Onslow County and the secondary service area for the period October 2005 to September 2008. Table 13 is based on Exhibit 8, page 65 of the JDI Application. (Jt. Ex. 1, p. 526)

295. On page 527, the project analyst "made adjustments to some of the data based on the information reported in the 2007-2009 SMFP." (Jt. Ex. 1, p. 527) Even with the "adjustment," the Agency still concluded that JDI's average annual growth rate for this three-year time period was 14.9%. (Jt. Ex. 1, p. 527)

296. The Agency pointed out in the next sentence that Onslow Memorial Hospital had experienced a -5.1% decline in MRI procedures during this same period. (Jt. Ex. 1, p. 527)

297. While the decline in growth in MRI scans at Onslow Memorial Hospital is some evidence of the MRI use in the county, it is not determinative of whether JDI demonstrated the

need for another fixed scanner. Despite Onslow Memorial Hospital's declining MRI volumes, the State Health Coordinating Council still included a need in the 2009 SMFP for an additional fixed MRI scanner in Onslow County. (Thorne-Williams, Vol. 5, p. 894)

298. The CON Section cannot overrule a need determination in the SMFP and the CON Section cannot substitute its judgment for the State Health Coordinating Council's. (Alexander, Vol. 12, p. 2327). Likewise, applicants have to rely upon the best information available to them at the time of the submission and cannot supplement or change the applications once submitted, even if better and more up to date information becomes available.

299. Despite its own decline in growth, Onslow Memorial Hospital supported the addition of a fixed scanner at OMLLC, which would be a competitor to OMH in the MRI market. (Jt. Ex. 3, Exhibit 18 (letter of support from Ed Piper, Ph.D., CEO of Onslow Memorial Hospital, to Dr. Elizabeth D'Angelo)

300. On page 527 of the Agency File, the Agency referred to JDI's 5% annual growth rate based on statewide use rate growth between 2004 and 2007. The Agency noted on the bottom of page 527 of the Agency File that the annual percentage change in MRI scan volume growth is decreasing, and that the percent change from 2006 to 2007 was 2.30% "which is the lowest percent change since 2000." (Jt. Ex. 1, p. 527) (Emphasis added)

301. JDI's 5% use rate growth (Jt. Ex. 2, p. 67) is actually smaller than any of the years shown on Table 14, with the exception of 2007, which had a percent change of 2.3%. Ms. Alexander acknowledged that one year does not make a trend. (Alexander, Vol. 13, p. 2457)

302. The Agency's Table 14 on page 527 of the Agency File shows, in each year between 1999 and 2007, the population of North Carolina has risen and with it, the number of MRI scans. (Jt. Ex. 1, p. 527)

303. The fact that the <u>percentage</u> increase is smaller in 2007 than it was in 2000, for example, does not change the fact that the actual MRI volumes are rising statewide. The actual number of MRI's being performed has significantly more relevance than a percent of change, especially when considering that a minimum number of MRI's performed (4118 weighted scans) must be projected by year 3 in order to meet the requirements.

304. On page 528 of the Agency File, the Agency states

> . . . the applicant states that the total MRI scans for the proposed service area increased by 13.76% CAGR (analyst corrected calculation showed the Total MRI scans CAGR to be 12.16%, based on the data pro vided by the applicant, and not 13.76%) and that its population increased by 1.43% during this timeframe.

(Jt. Ex. 1, pp. 527-528)

305. The Agency refers to the same incorrect CAGR calculation that it used on page 519 of the Agency File. The Agency stipulated that this was an error. *See* Stipulation 4 which refers to Stipulation 1.

306. At the end of the above-quoted passage, the Agency concluded on page 528 of the Agency File that "[t]herefore, projections based on this use rate assumption are unreliable." (Jt. Ex. 1, p. 528) When asked whether she still agreed with this statement, the project analyst, Bernetta Thorne-Williams was not sure. (Thorne-Williams, Vol. 5, p. 904)

307. On page 528 of the Agency File, the Agency next discusses Camp Lejeune and states that "[t]he applicant did not adequately demonstrate that one-third of the military personnel, who reside at Camp Lejeune, will travel off the military base in sufficient numbers to reach the market shares projected by CDI. . . .Therefore, it is just as likely that those seeking MRI services not offered at the Naval Hospital Camp Lejeune would opt to receive those

services at Onslow Memorial Hospital which is closer to the military base than the services proposed by CDI." (Jt. Ex. 1, p. 528)

308. The Agency stipulates that:

> . . . the Agency erred by not accepting JDI's representation that one third of JDI's patient population is military and further erred in stating that "[t]herefore, it is just as likely that those seeking MRI services not offered at the Naval Hospital Camp Lejeune would opt to receive those services at Onslow Memorial Hospital which is closer to the military base than the services proposed by CDI."

See Stipulation 5.

309. On page 529 of the Agency File, the Agency inserted Table 15 which depicts JDI's projected service area demand. (Jt. Ex. 1, p. 529)

310. In the narrative below Table 15, the Agency wrote that ". . . the 5% increase in MRI scans/1,000 per year is unsupported and unreliable by North Carolina historical data." (Jt. Ex. 1, p. 529)

311. At trial, Ms. Alexander testified that she was not clear where the 2008 "starting" use rate of 64.2 scans/1,000 population came from. (Alexander, Vol. 13, p. 2413) However, this criticism is not contained in the findings. (Alexander, Vol. 13, p. 2413-2412)

312. The basis for the 5% increase in MRI scans/1,000 per year is explained on page 67 of the JDI Application:

> As shown in Exhibit 10, below, to project MRI demand in the overall service area, CDI applied a conservative annual growth rate of 5 percent, based on the statewide use rate growth between 2004 and 2007. Using this growth rate, the projected use rate for MRI scans per 1,000 population in the service area increased for 64.2 in 2008 to 78.0 in 2012, Year 3 of the proposed project.

(Jt. Ex. 2, p. 67)

313. The 5 percent increase per year in MRI scans/1,000 population is mathematically correct. The math of how one gets to 64.2 in 2008 (page 67 of the application) is as follows: On page 62 of the application, JDI shows that the use rate/1,000 population in the service area in 2006 was 58.2. The difference between 2006 and 2008 (the starting year on page 67) is two years.

314. Applying 5% to each of those two years, one reaches 64.2 scans /1,000 population in the service area:

> 58.2 x 1.05 = 61.11
> 61.1 x 1.05 = 64.16, which rounds to 64.2

315. The last year that one could obtain "good data" from the Medical Facilities Planning Section was 2006. (Alexander, Vol. 12, p. 2382) That is why the use rate/1,000 on page 62 stops at 2006.

316. In fact, footnote 7 on page 61 of the JDI Application states "[t]he 2007 patient origin data for fixed MRI is not complete, and therefore was not used in this analysis." (Jt. Ex. 2, p. 61) The 2006 use rate is the *actual* use rate data available from the State. (Platt, Vol. 9, p. 1704)

317. On page 59 of the application, JDI stated:

> The MRI use rate in North Carolina has also increased from 47.60 procedures per 1,000 population to 90.87 procedures per 1,000 population, representing an average annual increase of 8.4 percent between 1990 and 2007. In more recent years, the rate of growth in the MRI use rate has slowed somewhat. **The average rate of increase in the use rate over the past four years (2004-2007) is six percent.** . . . The per capita use of MRI is expected to continue to grow as the diagnostic capability of MRI equipment expands. As the number of MRI procedures per capita increases, the demand for MRI services in the service area will also increase over time. Increases in MRI

> use rates in the service area are expected to parallel the trends experienced statewide . . . .

(Jt. Ex. 2, p. 59)(Emphasis added).

318. By choosing a 5 percent use rate growth instead of the statewide average six percent use rate growth from 2004 to 2007, JDI took a more conservative approach.

319. When Ms. Thorne-Williams was asked whether she had any reason to question any of the numbers on Table 15, she answered "[n]ot at this time." (Thorne-Williams, Vol. 5, p. 906)

320. The Agency's conclusion on page 529 of the Agency File that "the 5% increase in MRI scans/1,000 per year is unsupported and unreliable by North Carolina historical data" is not correct.

321. On page 529 of the Agency File, the Agency wrote that JDI's physician letters of support "do not support a 12% increase in scans in Yr 2 or an 8% increase in Yr 3." (Jt. Ex. 1, p. 529) Ms. Alexander acknowledged that JDI did not use its letters of support as part of its need methodology. (Alexander, Vol. 13, pp. 2463; 2466)

322. The Agency found the letters of support conforming with the rule at 10A NCAC 14C .2702(c)(6) which requires an applicant to provide "letters of support 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." (Jt. Ex. 1, p. 586)

323. The Agency stipulated:

> A 1:1 correlation between the volume projections and the number of estimated referrals in the physician letters of support is not required.

See Stipulation 6.

324. At the end of its discussion on Criterion 3, the Agency recognized on page 529 of the Agency File that JDI exceeded the performance standard at 10A N.C.A.C. 14C.2703(b)(3) of 4,118 weighted MRI scans in Year 3; however, the Agency went further and concluded that the "number of MRI procedures are not based on reasonable assumptions and methodology. Therefore, the number of weighted MRI procedures during the third operating years [sic] is unsupported and unreliable." (Jt. Ex. 1, pp. 529-530)

325. At trial, when Project Analyst Ms. Thorne-Williams was asked what was not reasonable about the assumptions that JDI employed in this application, she could not recall. Generally she was not able to defend the conclusions she wrote for Criterion 3. (Thorne-Williams, Vol. 5, pp. 906-908)

326. JDI contends that at trial, the Agency offered new reasons and/or rationalization as to why the JDI application should be disapproved.

327. It not appropriate for the Agency to offer reasons or rationalizations beyond what is stated in the Findings in order to disapprove an application and, to the degree that any is offered here, it is not to be considered. It is recognized that proffered testimony and/or exhibits may have been admitted into evidence which may tend to support "new" reasons or rationalizations, and to that end the appropriate weight is given. However, for the sake of completeness, the Court will discuss purported lost patients, an incorrect base, and Agency Exhibit 13, which JDI contends are the new reasons being offered by the Agency.

i. The purported 400 "lost" patients

328. At trial, the Agency attempted to show that 400 patients who went to JDI in 2008 have been "lost" and should not be factored into the patients JDI projects to serve in Years 1-3 of

the project. (Thorne-Williams, Vol. 6, p. 1009; Alexander, Vol. 11, p. 2182) This number is derived by adding the total number of patients from Carteret (146), Craven (89) and "Other" (165) that JDI served in 2008. (Jt. Ex. 2, p. 77)

329. Although there is discussion in the Agency Findings about Carteret and Craven counties, there is no discussion of 400 patients that are unaccounted. (Jt. Ex. 1, pp. 513-514)

330. Patients from Carteret and Craven have been accounted for in the findings narrative and previously in this decision. They have been accounted for in the "Other" category which accounts for patients for whom service is rendered but who do not come from one of the specifically enumerated counties. The Carteret and Craven county residents are reflected in the total of "Other" patients, as shown on page 78 of the JDI Application and the footnote. The Agency acknowledged at trial that JDI will likely continue to serve some patients from Carteret and Craven Counties.

331. The inclusion of "Other" in the 400 allegedly unaccounted patients is not supported. The application expressly states on page 78 that JDI will serve some patients from "Other" which includes a diverse range of counties from all over North Carolina that contribute some patients to JDI's annual total. (Jt. Ex. 2, p. 67) It is consistent with the historical MRI patient origin information that the Agency obtained and placed at pages 165 and 166 of the Agency File.

332. The Agency offered no evidence at trial to show that JDI would not serve patients from "Other."

333. In the JDI Application, the 400 patients are already accounted for as part of the base number. Ms. Platt testified that if the 400 patients were taken "out," as the Agency

suggested, they would have to be added back in as in-migration (*i.e.,* patients from outside the service area seeking service at JDI):

334. Ms. Platt went on to testify:

> A. It would be more than 400 because as JDI's volume has grown over time, the growth has come not only from the service area but from other counties as well. And you would continue that trend to see the overall growth of JDI, both from patients within the service area and from outside the service area.

(Platt, Vol. 9, pp. 1714)

335. Ms. Platt calculated that the growth just in Onslow residents served by JDI in 2008 (4,174) and projected to be served in Project Year 1 (5,842) would be 1,688 and that would be more than sufficient to make up for any perceived shortfall of 400 patients "lost." (Platt, Vol. 10, p. 1744)

336. Ms. Platt explained that if one leaves the JDI methodology exactly as it is with the in-migration is already built in or whether one treats the 400 patients as in-migration and adds the 400 patients back in, the net result is strikingly similar.

ii. An incorrect "base"

337. At trial, the Agency also suggested that the "base" number of procedures that JDI used to develop the projections (4,887) was not correct. (Jt. Ex. 2, p. 67) This assertion is not found in the Agency Findings. (Alexander, Vol. 12, p. 2380)

338. The issue of base is somewhat incorporated into the presentation on "Population Proposed to be Served" beginning on page 58 above.

339. Ms. Platt testified in response to the Agency's questions that she feels that the starting number is correct. She acknowledges that there are multiple methods to arrive at the

starting number but that she chose this method for simplicity and that it is based on JDI's actual utilization.

340. As Ms. Platt's testimony and JDI Exhibit 98 show, regardless of how one treats the 400 patients from Carteret, Craven and "Other," the result ends up at a very similar point by Year 3, *i.e.*, 33.6% market share if in-migration is built in versus 32.3% if in-migration is added back in.

iii. Agency Exhibit 13

341. Ms. Alexander created Agency Exhibit 13 in an effort to refute Ms. Platt's testimony. Exhibit 13 was not in the decision or the Agency File.

342. Ms. Alexander acknowledged that Agency Exhibit 13 was not rebuttal evidence and that she had all the information needed to create Exhibit 13 in the application and Agency File. It functions as additional support for the Agency's decision:

343. Exhibit 13 is incorrect because Ms. Alexander mistakenly used 2.5% instead of applying a 5% growth rate to the numbers on page 67 of the JDI Application in 2009-2010, (Alexander, Vol. 13, page 2504)

344. This was incorrect because it did not give JDI credit for a full year's worth of growth; it only gave JDI credit for 6 months of growth. Using the lower, incorrect base, JDI would fail to meet the performance standard of 4,118 weighted MRI scans in Year 3. Ms. Alexander consistently used five percent in Agency Exhibit 13, except for the 2009-2010 time period. (Agency Ex. 13; Alexander, Vol. 13, Vol. 13, p. 2504) Ms. Alexander acknowledged her mistake at trial.

345. As the Court noted in its brief examination of Ms. Alexander, the time period between the end of 2009 and the end of Project Year 1 (June 30, 2011) would actually be

eighteen months. (Alexander, Vol. 13, pp. 2573-2574). This would further tend to support the reasonableness of using 5%, instead of the 2.5% used by Ms. Alexander as the use rate growth, which only gave JDI credit for 6 months' of growth.

3. **CRITERION 4**

346. Criterion 4 requires an applicant to demonstrate that its proposal is an effective alternative method of meeting the needs for the proposed project. (Jt. Ex. 1, p.552)

347. The Agency's discussion under Criterion 4 states that the JDI Application is nonconforming with Criterion 4 because of its nonconformity with Criteria 1, 3, 5, 6, 18a and 10A N.C.A.C. .2700 (Jt. Ex. 1 at 552)

348. Had JDI been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 4. Thus, the Agency's finding of non-conformity under Criterion 4 for the JDI Application was a derivative of other findings. See id.; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; also see OMLLC Ex. 144, p. 5.

349. Therefore, if the Agency erred in its determination that the JDI Application was non-conforming with Criteria 1, 3, 5, 6, 18a, as well as the Agency Rules, the JDI Application would be conforming with Criterion 4.

4. **CRITERION 5**

350. Criterion 5 requires an applicant to 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. (Jt. Ex. 1 at 553)

351. The Agency found that JDI had demonstrated the availability of funds for capital needs of the project. (Jt. Ex. 1 at 554)

352. The Agency concluded, however, that JDI failed to demonstrate the financial feasibility of the project based upon reasonable projections of costs and revenues. (Jt. Ex. 1 at 559)

353. JDI failed to include in its application certain requested historical financial information. While this requirement under the application is not an Agency Rule and did not result in the finding of nonconformity under Criterion 5, including such information is helpful to the Agency to in assessing the financial feasibility of the proposed project. (Jt. Ex. 1, p. 556) (Alexander, Tr., Vol. 13, pp. 2481-82)

354. The Agency acknowledged errors in its analysis of the JDI Application under Criterion 5. Accordingly, the Agency stipulated prior to hearing that the JDI Application included professional fees. (Stipulation 9) (Jt. Ex. 1, at 556) Likewise, Ms. Alexander testified that the Agency incorrectly applied the entire facility's payor mix to the MRI procedures, resulting in the erroneous conclusion that JDI underestimated its contractual allowance by over 3 million dollars. (Alexander Tr., Vol.--, p.) (Jt. Ex. 1 at 559)

355. However, the Agency found the JDI Application nonconforming with Criterion because the applicant's financial projections were premised upon the need analysis discussed under Criterion 3, which the Agency determined was unreasonable. Thus, given the fact that the assumptions underlying the financial projections were deemed unreasonable, the Agency concluded that JDI failed to document the financial feasibility of the facility due to its nonconformity with Criterion 3. (Jt. Ex. 1 at 559)

356. Had JDI been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 5. Thus, the Agency's finding of non-conformity under Criterion 5

for the JDI Application was a derivative of other findings. <u>See</u> <u>id.</u>; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; <u>also</u> <u>see</u> OMLLC Ex. 144, p. 5.

357. Therefore, if the Agency erred in its determination that the JDI Application was non-conforming with Criteria 3, the JDI Application would be conforming with Criterion 5.

5. **<u>CRITERION 6</u>**

358. Criterion 6 requires the applicant to demonstrate that the proposed project will not result in the unnecessary duplication of services. (Jt. Ex. 1 at 565)

359. The Agency's discussion under Criterion 6 states that the JDI Application is non-conforming with Criterion 6 because of its nonconformity with Criteria 3. (Jt. Ex. 1 at 565-66)

360. Had JDI been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 6. Thus, the Agency's finding of non-conformity under Criterion 6 for the JDI Application was a derivative of other findings. <u>See</u> <u>id.</u>; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; <u>also</u> <u>see</u> OMLLC Ex. 144, p. 5.

361. Therefore, if the Agency erred in its determination that the JDI Application was non-conforming with Criteria 3, the JDI Application would be conforming with Criterion 6.

6. **<u>CRITERION 7</u>**

362. Criterion 7 requires an applicant to adequately demonstrate the availability of health manpower, management and other resources needed for the operation of the proposed services. (Jt. Ex. 1 at 566)

363. The JDI Application outlined the current and projected administrative, clinical and support staff needed for the proposed MRI services for the first three years of the project. (Jt. Ex. 3, pp. 104-106) (Jt. Ex. 1, p. 566)

364. The Agency concluded that JDI adequately demonstrated the availability of health manpower, management and other resources needed for the operation of the proposed MRI services. (Jt. Ex. 1 at 568)

7. **CRITERION 8**

365. Criterion 8 requires the applicant to adequately demonstrate the availability of ancillary and support services, and demonstrate that the proposed service will be coordinated with the existing health care system. (Jt. Ex. 1 at 570)

366. The Agency concluded that the JDI Application adequately demonstrated the availability of ancillary and support services, and demonstrated that the proposed service will be coordinated with the existing health care system. (Jt. Ex. 1 at 570)

8. **CRITERION 13a**

367. Criterion 13a requires an applicant to show that the medically underserved populations currently using the applicant's existing services have access to the existing services.

368. The Agency noted that the JDI Application included a copy of its existing policy of nondiscrimination, a payor mix for the entire existing facility, the existing MRI services for FY 2008, MedQuest's Billing and Admissions Policy, and the amount of bad debt and charity care for the entire facility for FY 2008. (Jt. Ex. 1, pp. 574-75)

369. After considering the information provided by the applicant, the Agency concluded that JDI adequately demonstrated that the medically underserved population currently has access to the MRI services provided at JDI, and conformed to Criterion 13a. (Jt. Ex. 1 at 575)

9. **CRITERION 13b**

370. Criterion 13b requires an applicant to demonstrate it has historically met its obligation requiring provision of uncompensated care, community service, or access by minorities and handicapped persons receiving federal assistance.

371. The JDI Application reported that during the past 5 years, no civil rights actions have been filed against JDI, MedQuest or Novant Health, Inc. (Jt. Ex. 1 at 576)

372. The Agency concluded that the JDI Application adequately demonstrated that it has not discriminated in providing of services to minorities, handicapped persons or persons receiving federal assistance, and determined that the OMLLC Application conformed to Criterion 13b. (Jt. Ex. 1 at 576)

10. CRITERION 13c

Criterion 13c

N.C. Gen. Stat. § 131E-183(a)(13)(c) ("Criterion 13c") provides that:

> (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 extend to which the proposed service will be accessible, the applicant shall show:
>
> 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.

373. Criterion 13, which addresses service to the medically underserved, has four subparts. JDI was found conforming with three of the four subparts. (Jt. Ex. 1, pp. 575-576;

581) The Agency concluded, however, that JDI was non-conforming with Criterion 13c. (Jt. Ex. 577-579) Criterion 13c requires the applicant to demonstrate that its project will serve the medically underserved. Criterion 13c is forward-looking.

374. As used in Criterion 13, the term "medically underserved" means medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons.

375. Significantly, the Agency found JDI conforming with Criterion 13a, which requires the applicant already involved in providing the service to demonstrate its past performance in serving the medically underserved. (Jt. Ex. 1, p. 575)

376. Ms. Alexander could not cite any findings in which an applicant that had been found conforming with Criterion 13a was found non-conforming with Criterion 13c. (Alexander, Vol. 13, pp. 2492; 2494)

377. Likewise, David Meyer, OMLLC's expert, could not name any set of findings in which an applicant that had been found conforming with Criterion 13a was found non-conforming with Criterion 13c. (Meyer, Vol. 7, pp. 1224-1225)

378. In its discussion of Criterion 13c, the Agency also noted that JDI would partner with the Caring Community Clinic in Jacksonville to provide 100 to 150 free scans annually to uninsured residents of Onslow County. (Jt. Ex. 1, p. 577) The Agency believed these free scans would have some monetary value. (Thorne-Williams, Vol. 6, p. 962)

379. The Agency also noted that JDI included a copy of its charity care policy. The Agency reviewed the charity care policy and no problems with it. (Thorne-Williams, Vol. 6, pp. 962-963)

380. The Agency also noted JDI's estimated charity care and bad debt in Table 27 and expressed no concerns about these numbers. (Jt. Ex. 1. p. 577) (Thorne-Williams, Vol. 6, pp. 966-967)

381. Moreover, the Agency found JDI conforming with the "equitable access" prong of Criterion 1, which also deals with service to the medically underserved. (Jt. Ex. 1, p. 508)

382. Ms. Alexander confirmed that the same group of medically underserved people is addressed under the "equitable access" prong of Criterion 1 and Criterion 13c. (Alexander, Vol. 13, pp. 2494-2495) Thus, the findings themselves are somewhat internally inconsistent.

383. The Agency's finding of non-conformity under Criterion 13c rests solely on the classification of Champus/TriCare beneficiaries, as demonstrated in Tables 25 and 26 on page 578 of the Agency File:

384. These tables are consistent except that in Table 25, the Managed Care category constitutes 63.7% of patient days and the Other (Workers Comp) category accounts for 4.1% of patient days for a total of these two figures of 67.8%; whereas in Table 26, the Managed Care category constitutes 21.8% of patient days and the Other (Workers Comp) category accounts for 46.0% of patient days. The total of these two figures also is 67.8%.

385. The difference in the two tables is that Champus/TriCare was moved from the Managed Care category in Table 25 to the Other (Workers Comp) category in Table 26.

386. A footnote to Table 25 explains that Managed Care includes Champus/TriCare which covers military personnel and their families.

387. In the pro formas to the JDI Application, page 142, footnote 2 states that Champus/TriCare is in the "Other" category: "The Projected Average Reimbursement Rate ($700.22) is average of the projected reimbursement for MRI scans for all Commercial Insurance

payors, Managed Care Payors and Other payors (including Champus/TriCare, Third Party Administrator and Workers' Compensation)." (JDI Ex. 34, pp. 1956-1957)

388. As Ms. Platt, JDI's expert witness explained, Champus/TriCare can be reflected in either the Managed Care category or in the "Other" category. (Platt, Vol. 8, p. 1471)

389. OMLLC classified Champus/TriCare in "Other" in its payor mix. Dr. Everett and Dr. D'Angelo testified that it could also be classified in managed care. (Jt. Ex. 3, p. 90; Everett, Vol. 10, p. 1833; D'Angelo, Vol. 10, p. 1881)

390. Team Leader Ms. Alexander acknowledged that Champus/TriCare *is not* a category of medically underserved patients with respect to JDI because JDI serves many Champus/TriCare beneficiaries. (Alexander, Vol. 13, pp. 2495-2496); *see also* Stipulation 5, which acknowledges that one-third of JDI's patient population is military.

11. CRITERION 13d

391. Criterion 13d requires an applicant to offer a range of means by which a person will have access to its services. (Jt. Ex. 1 at 580)

392. The Agency noted that the JDI Application demonstrated that patients would have access to the proposed services by physician referrals and the Caring Community Clinic, and concluded that the JDI Application was conforming to Criterion 13d. (Jt. Ex. 1 at 580-81)

12. CRITERION 14

393. Criterion 14 requires an applicant to demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable. (Jt. Ex. 1 at 581)

394. The Agency noted that the JDI Application expressed willingness to accommodate student training programs, and included copies of existing clinical agreements between JDI and local schools. (Jt. Ex. 1 at 581)

395. After considering the information provided in the JDI Application, the Agency concluded that the applicant demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area, and determined that the JDI Application was conforming to Criterion 14. (Jt. Ex. 1 at 582)

13. **CRITERION 18a**

396. Criterion 18a requires the applicant to demonstrate that the proposed service would have a positive impact upon the cost effectiveness, quality, and access to the proposed services. (Jt. Ex. 1 at 583)

397. The Agency's discussion under Criterion 6 states that the JDI Application is nonconforming with Criterion 6 because of its nonconformity with Criteria 1, 3, 4, 5, 6, and 13c (Jt. Ex. 1 at 583)

398. Had JDI been found conforming with the other Statutory Review Criteria and the Agency Rules, then the Agency would have determined that the OMLLC Application was conforming with Criterion 18a. Thus, the Agency's finding of non-conformity under Criterion 18a for the JDI Application was a derivative of other findings. See id.; Thorne-Williams, Tr. pp. 732; Alexander, Tr. pp. 2171-72; also see OMLLC Ex. 144, p. 5.

399. Therefore, if the Agency erred in its determination that the JDI Application was non-conforming with Criteria 1, 3, 4, 5, 6, and 13c, the JDI Application would be conforming with Criterion 18a.

14. **CRITERION 20**

400. Criterion 20 requires an applicant already involved in the provision of health services to provide evidence that the applicant has provided quality care provided in the past. (Jt. Ex. 583)

401. The Agency noted that the JDI Application provided evidence that JDI is a certified provider of Medicare and Medicaid, that their existing scanners are accredited by the American College of Radiologist, and that it anticipates the proposed MRI scanner will likewise be accredited. (Jt. Ex. 1, 583-84)

402. After considering the information provided by the applicant, the Agency determined that the JDI Application was conforming to Criterion 20.

B. REGULATORY REVIEW CRITERIA

403. In its Findings, the Agency determined that the JDI Application was non-conforming with 10A N.C.A.C. 14C .2702(c)(8), .2702(c)(9), and .2703(b)(3).

404. Under 10A N.C.A.C. 14C .2702(c)(8) the applicant is required to provide certain data concerning the number of un-weighted procedures for the four types of MRI procedures identified in the SMFP. (Jt. Ex. 1, p. 587) Because the JDI facility provides only outpatient services, the Agency stipulated that it was error to find the JDI Application nonconforming to these rules. (Stipulation 12)

405. Under 10A N.C.A.C. 14C .2702(c)(9) the applicant is required to provide certain data concerning the number of weighted procedures for the four types of MRI procedures identified in the SMFP. (Jt. Ex. 1, p. 587) Because the JDI facility provides only outpatient services, the Agency stipulated that it was error to find the JDI Application nonconforming to these rules. (Stipulation 13)

406. Under 10A N.C.A.C. 14C .2703(b)(3), the JDI Applicant was required to project at least 4,118 weighted scans on the proposed MRI scanner by the end of the third year of operation. (Agency Ex. 1, pp. 598-99)

407. The Agency concluded that JDI projected to perform 4,211 weighted procedures during in third year of operations following the completion of the proposed project. (Jt. Ex. 1, pp. 598-99) (Jt. Ex. 2, p. 44)

408. The Agency nonetheless determined, due to its finding that JDI failed to adequately document the reasonableness of its projected volumes and utilization under Criterion 3, that the JDI Application was non-conforming with 10A N.C.A.C. 14C .2703(b)(3). (Jt. Ex. 1, pp. 598-99)

409. Ms. Alexander testified that, had JDI been found conforming with Criterion 3, then the Agency would have determined that the JDI Application was conforming with 10A N.C.A.C. 14C .2703(b)(3). (Alexander Tr., Vol. 12, p. 2219)

III. COMPARATIVE ANALYSIS

410. When competitive applications are reviewed by the Agency, the Agency conducts a comparative analysis. The Agency conducted a comparative analysis in this case because the OMLLC Application and the JDI Application were competitive.

411. If an application is non-conforming with the statutory review criteria or the regulatory review criteria and the Agency has determined that it cannot be conditionally approved, the application will be denied.

412. In a competitive review, an application that is non-conforming and is not conditionally approvable cannot be comparatively superior to an application that is conforming with all of the statutory and regulatory review criteria.

413. There is no statute or rule which requires the Agency to identify certain comparative factors. The CON law simply states that the Agency must provide notice of all "findings and conclusions upon which it based its decision." N.C. Gen. Stat. § 131E-186(b).

The "findings and conclusions" in the Comparative Analysis which are not specifically addressed in the statutory criteria and rules allow the Agency the opportunity to explain why it finds one applicant preferable to another on a comparative basis. See Britthaven, Inc. v. North Carolina Dept. of Human Resources, Div. of Facility Services, 118 N.C. App. 379, 455 S.E.2d 455, 461 (1995). Generally, the Agency selects the comparative factors in each review which it believes are the most appropriate, based on the facts or circumstances in that particular review. See Thorne-Williams, Tr. p. 734.

414. It is within the Agency's discretion to choose which comparative factors the Agency will use in any given review.

415. In the comparative analysis, the Agency did not find that one applicant was superior, and both the OMLLC Application and the JDI Application were denied. (Jt. Ex. 1 at 612-613)

Based upon the foregoing Findings of Fact, the Court makes the following

CONCLUSIONS OF LAW

1. To the extent that certain portions of the foregoing Findings of Fact constitute mixed issues of law and fact, such Findings of Fact shall be deemed incorporated herein by reference as Conclusions of Law.

2. A court need not make findings as to every fact which arises from the evidence and need only find those facts which are material to the settlement of the dispute. Flanders v. Gabriel. 110 N.C. App. 438, 449, 429 S.E. 2d 611, 612 (1993).

3. All parties have been correctly designated and there is no question as to misjoinder or nonjoinder of parties.

4. The Office of Administrative Hearings has jurisdiction over all of the parties and the subject matter of this action.

5. To obtain a CON for a proposed project, a CON application must satisfy all of the review criteria set forth in N.C. Gen. Stat. § 131E-183(a). If an application fails to conform with any one of these criteria, then the applicant is not entitled to a CON for the proposed project as a matter of law. *See Presbyterian-Orthopaedic Hospital v. N.C. Dept. of Human Res.*, 122 N.C. App. 529, 534-35, 470 S.E.2d 831, 834 (1996).

6. As Petitioner in case 09 DHR 5617, OMLLC has the burden of proof on issues presented to the Court regarding the Agency's disapproval of the OMLLC Application. See *Southland Amusements and Vending, Inc. v. Rourk*, 143 N.C. App. 88, 94, 545 S.E.2d 254, 257 (2001).

7. OMLLC Application failed to comply with N.C. Gen. Stat. § 131E-183(a)(1) ("Criterion 1"), which requires the proposed project to be "consistent with applicable policies and need determinations in the State Medical Facilities Plan . . . ."

8. Policy GEN-3 in the 2009 SMFP is applicable to the review of the OMLLC Application.

9. Policy GEN-3 requires a CON application to: (1) promote safety and quality; (2) promote equitable access; and (3) maximize health care value. (Alexander Tr., Vol. 11 at 2115)

10. The Agency correctly found that OMLLC did not adequately demonstrate the need for its proposed project under Criterion 3, and did not demonstrate that its project is financially feasible under Criterion 5; and, based on the same reasoning, OMLLC did not demonstrate the process by which it plans to maximize healthcare value expended under Criterion 1.

11. OMLLC's Application failed to comply with N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3"), which requires an applicant to "identify the population to be served by the proposed project and [the applicant] shall demonstrate the need that this population has for the services proposed . . . ."

12. OMLLC's Application failed to comply with Criterion 3 because it failed to demonstrate the need the identified population has for the services proposed.

13. OMLLC's Application failed to comply with N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4"), which requires an applicant to demonstrate that the "least costly or most effective alternative has been proposed."

14. OMLLC's Application failure to comply with Criterion 4 is derivative of OMLLC's failure to be conforming to Criteria 3 and 5, as well as other derivative Criteria, and, therefore, failed to demonstrate that its project is an effective alternative.

15. OMLLC's Application failed to comply with N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5"), which requires an applicant to demonstrate the "immediate and long term financial feasibility of the proposal, based upon reasonable projections of the costs and the charges for providing health services by the person providing the services."

16. OMLLC's Application is nonconforming with Criterion 5 because OMLLC failed to demonstrate the availability of sufficient funds for the capital and working needs of the project.

17. OMLLC's Application is also nonconforming with Criterion 5 due to its nonconformity with Criterion 3 and because OMLLC failed to demonstrate that the financial feasibility of its proposal was based upon reasonable assumptions regarding costs and revenues.

18. The OMLLC Application could have been found conditionally conforming with Criterion 5, with regard to the availability of funding for the project; however, OMLLC was found to be non-conforming to Criteria 3 as well.

19. OMLLC's Application failed to comply with N.C. Gen. Stat. § 131E-183(a)(6) ("Criterion 6") which requires an applicant to demonstrate that the proposed project will not cause an "unnecessary duplication of existing or approved health service capabilities or facilities."

20. OMLLC's Application failure to comply with Criterion 6 is derivative of OMLLC's failure to be conforming to Criteria 3, and therefore failed to prove the project is an unnecessary duplication of existing or approved MRI services in Onslow County.

21. OMLLC's Application is found to be conforming with N.C. Gen. Stat. § 131E-183(a)(7) ("Criterion 7") which requires an applicant to "show evidence of the availability of resources, including health manpower. . . ."

22. OMLLC's Application is conforming with Criterion 7 because the applicant sufficiently demonstrated the availability of resources and that expenses for all staff had been adequately budgeted. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 7.

23. OMLLC's Application is found to be conforming with N.C. Gen. Stat. § 131E-183(a)(8) ("Criterion 8") which requires an applicant to "demonstrate . . . the provision of necessary ancillary and support services."

24. OMLLC's Application adequately demonstrated the availability of ancillary and support services. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 8.

25. OMLLC's Application was properly found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(12) ("Criterion 12") which requires an applicant to "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 cost of providing health services..., and that applicable energy saving features have been incorporated into the construction plans."

26. OMLLC's Application was appropriately found to be conforming to N.C. Gen. Stat. § 131E-183(a)(13)(c) ("Criterion 13(c)") which requires an applicant to show that "the elderly and the medically underserved groups . . . 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 . . . ."

27. OMLLC's Application was appropriately found by the Agency conforming with N.C. Gen. Stat. § 131E-183(a)(13d) ("Criterion 13d"), which requires an applicant to "offer[] a range of means by which a person will have access to its services. ..."

28. OMLLC's Application was appropriately found by the Agency conforming with N.C. Gen. Stat. § 131E-183(a)(14) ("Criterion 14"), which requires an applicant to "demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable."

29. OMLLC's Application was appropriately found by the Agency to be nonconforming with N.C. Gen. Stat. § 131E-183(a)(18a) ("Criterion 18a"), which requires an applicant to "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 on the cost effectiveness, quality, and access to services provided. . . ."

30. OMLLC's Application's failure to comply with Criterion 18a is derivative of OMLLC's failure to be conforming to Criteria 3 and 5, as well as other derivative Criteria, and, therefore, failed to demonstrate that its proposed project will have a positive impact upon the cost effectiveness, quality and access to the proposed services. The Agency correctly and reasonably determined that the OMLLC Application was nonconforming to Criterion 18a.

31. OMLLC's Application was appropriately found by the Agency to be nonconforming with 10A N.C.A.C. 14C.2703 (b)(3) which requires an applicant to meet a performance threshold in the number of weighted MRI procedures during the third year of operation.

32. The OMLLC Application's failure to comply with Rule 10A N.C.A.C. 14C.2703 (b)(3) is derivative of OMLLC's failure to be conforming to Criteria 3, as well as other derivative Criteria, and, therefore, failed to demonstrate that that the assumptions used to project its volume were based upon reasonable or credible projections of utilization even though the applicant projected to perform 4,193 weighted procedures during its third year of operation. The Agency correctly and reasonably determined that the OMLLC Application was nonconforming to Rule 10A N.C.A.C. 14C.2703 (b)(3).

33. The Agency did not exceed its authority or jurisdiction, act erroneously, fail to use proper procedure, act arbitrarily or capriciously, fail to act as required by rule or law, or otherwise violate the standards in N.C. Gen. Stat. § 150B-23 in concluding that OMLLC's Application was nonconforming with Criteria 3 and 5, as well as the other derivative criteria there from.

34. As hereinbefore set forth in these Findings of Fact and Conclusions of Law, the Agency did exceed its authority or jurisdiction, act erroneously, fail to use proper procedure, act

arbitrarily or capriciously, fail to act as required by rule or law, or otherwise violate the standards in N.C. Gen. Stat. § 150B-23 in concluding that OMLLC's Application was nonconforming with Criteria 7 and 8, Rule 10A N.C.A.C. 14C.2703(b)(3), as well as to the degree error was found in the Findings of Fact even though the conclusory conformity with the Findings may not have changed.

35. Except as hereinbefore set forth in the Findings, in concluding that OMLLC's Application was conforming, standing alone, with Criteria 12, 13c, 13d, 14 as well 10A N.C.A.C.14C.2702(a), -.2702(b)(1), -.2702(c)(1), -.2702(c)(4), -.2702(c)(6), -.2702(c)(7), -.2702(c)(8), -.2702(c)(9) -.2702(c)(10), -.2702(c)(11), -.2702(c)(15), -.2703(b)(6), -.2704(b), -.2705(a), -.2705(c), -.2705(d)(1), -.2705(d)(2) and -.2705(g), the Agency did not exceed its authority or jurisdiction; act erroneously; fail to use proper procedure; act arbitrarily or capriciously; fail to act as required by rule or law; or otherwise violate the standards in N.C. Gen. Stat. § 150B-23.

36. As Petitioner in case 09 DHR 5638, JDI has the burden of proof on issues presented to the Court regarding the Agency's disapproval of the JDI Application. See *Southland Amusements and Vending, Inc. v. Rourk*, 143 N.C. App. 88, 94, 545 S.E.2d 254, 257 (2001).

37. JDI's Application complies with N.C. Gen. Stat. § 131E-183(a)(1) ("Criterion 1"), which requires the proposed project to be "consistent with applicable policies and need determinations in the State Medical Facilities Plan . . . ."

38. Policy GEN-3 in the 2009 SMFP is applicable to the review of the OMLLC Application. Policy GEN-3 requires a CON application to: (1) promote safety and quality; (2) promote equitable access; and (3) maximize health care value. (Alexander Tr., Vol. 11 at 2115)

39. JDI's Application complies with Policy GEN-3 of Criterion 1 because JDI demonstrated in its application the process by which it plans to maximize health care value expended.

40. The Agency incorrectly found that JDI did not adequately demonstrate the need for its proposed project under Criterion 3, and did not demonstrate that its project is financially feasible under Criterion 5; and, based on that same reasoning, JDI demonstrated the process by which it plans to maximize healthcare value expended under Criterion 1.

41. JDI's Application complies with N.C. Gen. Stat. § 131E-183(a)(3) ("Criterion 3"), which requires an applicant to "identify the population to be served by the proposed project and [the applicant] shall demonstrate the need that this population has for the services proposed . . . ."

42. JDI's Application complies with Criterion 3 because it appropriately identified the population to be served by the proposed project and because the applicant appropriately demonstrated the need the population has for the services proposed. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 3.

43. JDI's Application complies with N.C. Gen. Stat. § 131E-183(a)(4) ("Criterion 4"), which requires an applicant to demonstrate that the "least costly or most effective alternative has been proposed."

44. The Agency's finding of the JDI Application's failure to comply with Criterion 4 was derivative of JDI's failure to be conforming to Criteria 3 and 5, as well as other derivative Criteria there from. JDI's Application complies with Criterion 4 because it is conforming with Criteria 3 and 5, as well as other derivative Criteria there from, and JDI demonstrated that its

project is the least costly or most effective alternative. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 4.

45. JDI's Application complies with N.C. Gen. Stat. § 131E-183(a)(5) ("Criterion 5"), which requires an applicant to demonstrate the "immediate and long term financial feasibility of the proposal, based upon reasonable projections of the costs and the charges for providing health services by the person providing the services."

46. JDI's Application was found by the Agency to be nonconforming in part with Criterion 5 due to its nonconformity with Criterion 3. JDI is found to be conforming to Criteria 3, and JDI demonstrated that the financial feasibility of its proposal was based upon reasonable assumptions regarding costs and revenues. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 5.

47. JDI's Application complies with N.C. Gen. Stat. § 131E-183(a)(6) ("Criterion 6") which requires an applicant to demonstrate that the proposed project will not cause an "unnecessary duplication of existing or approved health service capabilities or facilities."

48. JDI's Application was found by the Agency to be nonconforming with Criterion 6 due to its nonconformity with Criterion 3. JDI is found to be conforming to Criteria 3, and JDI demonstrated that that the project would not result in an unnecessary duplication of existing or approved MRI services. The Agency incorrectly determined that the JDI application was nonconforming to Criteria 6.

49. JDI's Application was appropriately found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(7) ("Criterion 7") which requires an applicant to "show evidence of the availability of resources, including health manpower. . . ."

50. JDI's Application adequately demonstrated the availability of health manpower, management and other resources needed for the operation of the proposed MRI services and the Agency correctly and reasonably determined that the JDI Application conformed to Criterion 7.

51. JDI's Application was appropriately found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(8) ("Criterion 8") which requires an applicant to "demonstrate . . . the provision of necessary ancillary and support services."

52. JDI's Application adequately demonstrated the availability of ancillary and support services, and the Agency correctly and reasonably determined that the JDI Application conformed to Criterion 8.

53. JDI's Application was appropriately found by the Agency to be conforming to N.C. Gen. Stat. § 131E-183(a)(13)(a) ("Criterion 13(a)") which requires an applicant to show "[t]he extent to which the medically underserved populations currently use the applicant's existing services in comparison to the percentage of population in the applicant's service area which is medically underserved."

54. JDI's Application adequately demonstrated that the medically underserved population currently has access to the MRI services provided at JDI, and the Agency correctly and reasonably determined that the OMLLC Application conformed to Criterion 13a.

55. JDI's Application was appropriately found by the Agency to be conforming to N.C. Gen. Stat. § 131E-183(a)(13)(b) ("Criterion 13(b)") which requires an applicant to demonstrate it has historically met its "obligation ... requiring provision of uncompensated care, community service, or access by minorities and handicapped person to programs receiving federal assistance ..."

56. JDI's Application adequately demonstrated that it has not discriminated in providing services to minorities, handicapped persons or persons receiving federal assistance, and the Agency correctly and reasonably determined that the OMLLC Application conformed to Criterion 13b.

57. JDI's Application is found to be conforming to N.C. Gen. Stat. § 131E-183(a)(13)(c) ("Criterion 13(c)") which requires an applicant to show that "the elderly and the medically underserved groups . . . 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. . . ."

58. The JDI Application appropriately demonstrated that the elderly and the medically underserved groups will have access to the proposed services, and the applicant's projected payor sources are reliable and reasonable. The Agency incorrectly determined that the JDI Application was nonconforming to Criterion 13c.

59. JDI's Application was appropriately found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(13d) ("Criterion 13d"), which requires an applicant to "offer[] a range of means by which a person will have access to its services. ..."

60. The JDI Application demonstrated that patients would have access to the proposed services, and the Agency correctly and reasonably determined that the JDI Application was conforming to Criterion 13d.

61. JDI's Application was appropriately found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(14) ("Criterion 14"), which requires an applicant to "demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable."

62. The JDI Application demonstrated that the proposed health services would accommodate the clinical needs of health professional training programs in the area, and the Agency correctly and reasonably determined that the JDI Application was conforming to Criterion 14.

63. JDI's Application is found to be conforming with N.C. Gen. Stat. § 131E-183(a)(18a) ("Criterion 18a"), which requires an applicant to "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 on the cost effectiveness, quality, and access to services provided. . . ."

64. The Agency's findings of the JDI Application's failure to comply with Criterion 18a is derivative of JDI's failure to be conforming to Criteria 3 and 5, as well as other derivative Criteria.

65. The JDI Application appropriately demonstrated that its proposed project will have a positive impact upon the cost effectiveness, quality and access to the proposed services. The Agency incorrectly determined that the JDI Application was nonconforming to Criterion 18a.

66. JDI's Application was appropriately found by the Agency to be conforming with N.C. Gen. Stat. § 131E-183(a)(20) ("Criterion 20"), which requires "[a]n applicant already involved in the provision of health services [to] provide evidence that quality care has been provided in the past.

67. The JDI Application provided evidence that the applicant historically had provided quality care, and the Agency correctly and reasonably determined that the JDI Application was conforming to Criterion 20.

68. JDI's Application is found to be conforming with 10A NCAC 14C.2702(c)(8) which requires an applicant to provide certain data concerning the number of un-weighted procedures for the four types of MRI procedures identified in the SMFP.

69. JDI's Application is found to be conforming with 10A NCAC 14C.2702(c)(9) which requires an applicant to provide certain data concerning the number of weighted procedures for the four types of MRI procedures identified in the SMFP.

70. JDI's Application is found to be conforming with 10A N.C.A.C. 14C.2703 (b)(3) which requires an applicant to meet a performance threshold in the number of weighted MRI procedures during the third year of operation.

71. The Agency's finding of the JDI Application's failure to comply with Rule 10A N.C.A.C. 14C.2703 (b)(3) is derivative of JDI's failure to be conforming to Criteria 3, as well as other derivative Criteria.

72. The JDI Application was found by the Agency to be nonconforming to 10A N.C.A.C. 2703(b)(3) even though the applicant projected to perform 4,211 weighted procedures during its third year of operation. JDI appropriately demonstrated and adequately documented the reasonableness of its projected volumes and utilization. The Agency incorrectly determined that the JDI Application was nonconforming to Rule10A N.C.A.C. 2703(b)(3).

73. The Agency did exceed its authority or jurisdiction, act erroneously, fail to use proper procedure, act arbitrarily or capriciously, fail to act as required by rule or law, or otherwise violate the standards in N.C. Gen. Stat. § 150B-23 in concluding that JDI's Application was nonconforming with Criteria 3 and 5, as well as the other criteria derivative there from and the Rules.

74. As set forth herein, in concluding that JDI's Application was conforming, standing alone, with Criteria 7, 8, 13a, 13b, 13d, 14, and 20 as well as 10A N.C.A.C.14C.2702(a), -.2702(b)(1), -.2702(c)(1), -.2702(c)(4), -.2702(c)(6), -.2702(c)(7), -.2702(c)(8), -.2702(c)(9), -.2702(c)(10), -.2702(c)(11), -.2702(c)(12), -.2702(c)(15), -.2703(b)(1), -.2703(b)(2), -2703(b)(5), -.2703(b)(6), -.2704(b), -.2705(a), -.2705(c), -.2705(d)(1) and -.2705(d)(2), the Agency did not exceed its authority or jurisdiction; act erroneously; fail to use proper procedure; act arbitrarily or capriciously; fail to act as required by rule or law; or otherwise violate the standards in N.C. Gen. Stat. § 150B-23.

75. If the Agency finds more than one applicant conforming to applicable review criteria, and the review is competitive, the Agency may employ a comparative analysis using factors of its choosing. *Craven Reg'l Med. Auth. v. N.C. Dep't of Health & Human Servs.*, 176 N.C. App. 46, 58, 625 S.E.2d 837, 845 (2006).

76. In the cases under consideration, since the Agency found neither applicant conforming, the Agency properly performed a comparative analysis.

77. The Agency should have found JDI conforming with the applicable review criteria and administrative rules. The Agency erred in disapproving the JDI Application.

78. The agency correctly found the OMLLC application to be nonconforming. Since the OMLLC Application is non-conforming and is not conditionally approvable, it cannot be comparatively superior to the JDI Application, which is conforming with all of the statutory and regulatory review criteria.

79. JDI is found to be the only applicant conforming to all criteria and rules and therefore is the superior applicant. No further comparative analysis is necessary.

80. In concluding that neither the OMLLC Application nor the JDI Application were the superior project, the Agency did exceed its authority or jurisdiction; act erroneously; fail to use proper procedure; act arbitrarily or capriciously; fail to act as required by rule or law; or otherwise violate the standards in N.C. Gen. Stat. § 150B-23.

81. The preponderance of the evidence does not support the Agency's comparative analysis and its conclusions that neither the OMLLC Application nor the JDI Application was comparatively superior and that neither applicant should be awarded the certificate of need to obtain and operate a fixed MRI in Onslow County.

BASED UPON the foregoing Findings of Fact and Conclusions of Law, the Undersigned makes the following:

RECOMMENDED DECISION

Based upon the foregoing Findings of Fact and Conclusions of Law, the Undersigned recommends that the decision of the Certificate of Need Section denying OMLLC's Application (Project I.D. No. P-8332-09) be **AFFIRMED**.

Further, based upon the foregoing Findings of Fact and Conclusions of Law, the Undersigned recommends that the decision of the Certificate of Need Section denying JDI's Application (Project I.D. No. P-8326-09) be **REVERSED** and that the Agency approve the JDI application.

ORDER

It is hereby ordered that the Agency shall serve a copy of the Final Decision on the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, NC 27699-6714, in accordance with N.C. Gen. Stat. § 150B-36(b).

NOTICE

Before the Agency makes the Final Decision, it is required by N.C. Gen. Stat. § 150B-36(a) to give each party an opportunity to file exceptions to this Recommended Decision, and to present written arguments to those in the Agency who will make the final decision.

The Agency is required by N.C. Gen. Stat. § 150B-36(b) to serve a copy of the Final Decision on all parties and to furnish a copy to the parties' attorneys of record. The Agency that will make the Final Decision in this case is the North Carolina Department of Health and Human Services.

IT IS SO ORDERED.

This the 24th day of June, 2010.

Donald W. Overby
Administrative Law Judge

A copy of the forgoing was mailed to each of the following:

S. Todd Hemphill
Matthew A. Fisher
Bode, Call & Stroupe, L.L.P.
Post Office Box 6338
Raleigh, NC 27628-6338

Denise M. Gunter
Candace S. Friel
Nelson Mullins Riley & Scarborough LLP
The Knollwood, Suite 530
380 Knollwood Avenue
Winston-Salem, NC 27103

June S. Ferrell
Juanita B. Tywford
Assistant Attorney General
North Carolina Department of Justice
PO Box 629
Raleigh, NC 27602

This the 24th day of June, 2010.

Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6714
Telephone: (919)431-3000
Facsimile: (919)431-3102

EXHIBIT

B

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

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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

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[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

[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.

[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.

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[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.]

MetLife, Inc. Application for the Acquisition of Control of The Travelers Insurance Company. Testimony before the Commissioner of Insurance of the State of Connecticut, June 2005. [Oral hearing testimony on behalf of MetLife]

Group Hospitalization and Medical Services, Inc. (GHMSI)/CareFirst Hearing. Testimony before the Department of Insurance, Securities and Banking, Washington, DC, March 2005. [Oral hearing testimony and written report on behalf of GHMSI]

Holmes Regional Medical Center, Inc. v. *Agency for Health Care Administration and Wuesthoff Memorial Hospital, Inc., State of Florida Division of Administrative Hearings, Tallahassee, FL,* December 2004. [Trial and deposition testimony on behalf of Holmes Regional Medical Center]

Application of The St. Paul Companies for the Acquisition of Control of Travelers Property and Casualty Corp. Testimony before the Commissioner of Insurance of the State of Connecticut, February 2004. [Oral hearing testimony on behalf of The St. Paul Companies and Travelers]

Anheuser-Busch Companies, Inc. Metal Container Corporation, and Anheuser-Busch, Inc. v. *Crown Cork & Seal Technologies Corporation.* U.S. District Court (Western District of Wisconsin), October 2003. [Deposition testimony on behalf of Crown Cork & Seal]

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]

United States v. *North Shore Health System and Long Island Jewish Medical Center.* U.S. District Court (Eastern District of New York), August 1997. [Trial and deposition testimony on behalf of the U.S. Department of Justice]

SELECTED EXPERT REPORTS AND WRITTEN TESTIMONY

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.

An Economic Analysis of Competition in the Title Insurance Industry. Report on behalf of Fidelity National Financial, Inc., submitted to the US GAO, March 20, 2006.

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)