Comments on the Duke Coley Hall Imaging Independent Diagnostic Testing Facility Certificate of Need Application, Project ID # J-12001-20

December 31, 2020

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), University of North Carolina Hospitals at Chapel Hill ("UNC Hospitals" or "UNC Health") submits the following comments related to Duke University Health System, Inc.'s ("Duke's") application to develop a diagnostic center with mammography and ultrasound equipment to be operated as an independent diagnostic testing facility ("IDTF") in Orange County. UNC Health's comments on this application include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, UNC Health has organized its discussion by issue, noting the Certificate of Need statutory review criteria creating the non-conformity on the application.

General Comments

While the specific issues with the application are identified in the sections to follow, UNC Health notes that the responses in the application fall far short of providing the minimum amount of information needed to demonstrate conformity with the applicable review criteria. The application includes multiple inconsistencies, lacks supporting analysis and assumptions, and provides insufficient documentation of the need for the proposed project, among other issues described below. Duke cannot simply remedy these problems through a response to these comments or otherwise since the information is not in the application and an applicant may not amend its application. Absent this information, the applicant fails to uphold its burden of demonstrating conformity with the criteria, and the application should be denied.

In summary, while the comments below address the specific issues in the application, the following reasons demonstrate why UNC Health believes the proposed project should be denied:

- The application has multiple inconsistencies, as well as missing and incorrect information.
- Duke repeatedly refers to its lack of an imaging center in Orange County, yet it projects the majority of its patients to come from other counties.
- Duke fails to consider or provide any discussion of why its existing facility at Patterson Place, located in the service area and just a few miles from the proposed location, cannot accommodate the projected utilization.
- Duke fails to demonstrate why other existing providers in the service area cannot accommodate the projected utilization and thus proposes a project that would unnecessarily duplicate existing health resources in the service area.
- Duke fails to demonstrate that its costs and charges are based on reasonable assumptions.

Given these issues, explained in more detail below, UNC Health believes the proposed project should be denied.

Issue-Specific Comments

1. Duke provides conflicting information regarding the scope of the proposed project.

   In Section C.1, the application describes the scope of the project as limited to mammography and ultrasound. However, in multiple locations the application refers to MRI services. On page 10, Section A.4.(f), the application states that the location has a contract for mobile MRI services. Throughout Section C.11., the application refers to the "proposed fixed MRI services." Exhibit K.2, the line drawings, also refer to the "Coley Hall MRI Study." The letter of support from the medical director in Exhibit I.3 refers to the "efforts to obtain a CON and develop a fixed MRI scanner," with no other services mentioned. While the applicant may assert that these are all simply typographical errors, they raise legitimate, unanswered questions regarding the nature of the project. In particular, even if the application is not attempting to propose a fixed MRI scanner as part of the project (given no *2020 SMFP* need determination for Orange County), if the site already provides contracted mobile MRI services as noted on page 10, which is certainly plausible, then why doesn't the application provide historical information that could be relevant to the proposed services, such as patient origin, payor mix and utilization/market share? Further, if the mobile MRI service will be operated as part of the IDTF, then why is that information missing from the financial pro formas in Section Q? If the mobile MRI services are not currently provided but will be in the future, will they be operated as part of the IDTF? There is no information in the Duke Application that answers these legitimate and important questions.

   The application also refers in multiple locations to the proposed facility as "the existing IDTF," or "the existing facility," including pages 24 and 49, and page 66 states that the IDTF is already certified by CMS and accredited, which also indicates an existing facility. The response to Section O.1 is incomplete (ends in the middle of sentence) and does not indicate whether the facility will be accredited or by whom or what metrics will be used to determine quality. The link to the ACR site provided in the application does not list a Duke facility in the ZIP code for the proposed facility; it does state that Wake Radiology has an existing, accredited facility that is a Breast Center of Excellence in that ZIP code, as discussed below. If the facility is existing, then it is not accredited, or if it does not exist, then the application fails to discuss if and how it will be accredited; in either case, the application is missing information needed for the review.

   Given these multiple references to a project involving MRI services and an existing facility, which appear to be more than a simple typo, it is unclear what Duke is actually proposing in terms of the full scope and nature of the services that will be provided at the proposed facility. Moreover, the responses in Section C.11 and Exhibit I.3 refer to MRI services and do not provide any responses for the proposed mammography and ultrasound services; as such, the application is incomplete.

   Based on these errors, the application should be found non-conforming with Criteria 3, 5, 6, 7, 8, 18a and 20.

2. Duke fails to adequately and consistently identify the patient population to be served.

In Section C.3, Duke presents its projected patient origin for the service components and the facility overall. These data are inconsistent with other portions of the application. First, the application presents the totals in the tables as the projected number of patients. However, they equal the projected number of procedures, by modality, in Section Q, page 6. On pages 25 and 26 of the application, Duke provides the patient to procedure ratios for the modalities: 1.27 for mammography and 1.25 for ultrasound. Therefore, the number of patients is not the same as the number of procedures, and the patient origin tables overstate the number of patients. This error further impacts total patient origin since the ratios are different for each modality and the number of procedures projected from each ZIP code is different for both modalities. This issue may also impact the financial projections, as it is unclear whether the projected revenue is based on patients or procedures.

Second, the projected patient origin is inconsistent with the assumptions in Section Q, which state that the in-migration percentage is 10 percent. In Section C.3, the application assumes that in-migration is only nine percent. Given this discrepancy, the accurate patient population to be served is unknown.

Finally, the in-migration patients, whether comprising nine percent, 10 percent or another number, are not identified by county or any other designation. The application states that they include patients from portions of Durham and Orange counties outside the service area, but it is unclear what portion of that number is projected from Durham and Orange. The counties that comprise the remainder of the in-migration percentage are also not provided. As such, Duke has failed to adequately identify the patient population it projects to serve.

Given these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a.

3. Duke fails to demonstrate the need of patients for the project.

In Section C.4, Duke states that the need for the proposed project includes historic [sic] growth, service area growth, DUHS strategic growth and the benefits of an IDTF. While all of these may be factors that led Duke to apply for the proposed project, none of them provide evidence of a patient-driven need for the development of a diagnostic center in Orange County, as explained below.

Historical change in Duke utilization: On page 22, Duke provides a table that it states provides evidence of "significant growth" in ultrasound and mammography services. This table fails to support the need for the proposed project, however, for multiple reasons. First, it provides data for Duke's existing facilities in Durham and Wake counties, without any documentation of the patient origin of those facilities, particularly that of Orange County residents and the growth (or decline) in their utilization of the services in Durham or Wake counties. In other words, the change in utilization at Duke's existing facilities in Durham and Wake counties do not indicate the need for a diagnostic center in Orange County. Second, from the discussion in the application, it appears that most of these

existing sites are hospital outpatient department ("HOPD") locations, some of which may be on a hospital campus. Thus, the trend may be driven by the existing location and/or the coordination with other services on those campuses, which would not be the same at the proposed Orange County location. Third, the apparent growth for annualized FY 21 is likely due to the compression of volume during the pandemic, not an actual growth trend. Duke acknowledges the negative impact of the pandemic on volume in FY 2020 but fails to acknowledge the impact of the restart of elective procedures in FY 2021. Finally, Duke notes that it believes an IDTF model is more cost-effective than the existing HOPD locations; however, both in this section and throughout the application, it fails to address the most obvious and less costly option of converting one or more existing HOPD locations to IDTF status.

Service area growth: While population growth can impact the utilization of healthcare services, on page 23, Duke projects the population of what it refers to as the "primary service area," including seven counties across central North Carolina. The patient origin tables in Section C.3 refer only to ZIP codes in Orange and Durham counties, with an unspecified "in-migration" category as noted above. It is therefore unclear why Duke considers a broad seven-county geography to be its primary service area, and Duke fails to explain how the growth in the other counties may impact the "need" for the proposed project.

Duke then presents projections from a third-party company for each of the ZIP codes within a 10-to-15-minute drive time. No other supporting analysis is provided; however, the compound annual growth rates for each service are 0.9 percent and 1.6 percent, respectively. Thus, the growth rate for mammography is lower than the population growth and ultrasound is slightly higher. As such, at a minimum, the population growth does not appear to be driving the growth for mammography utilization. Also lacking from the discussion in the application are the assumptions for whether the ultrasound procedures are for all settings or just scheduled, outpatient cases as proposed in the application. Given the volume, which is nearly three times that of mammography, it would appear that it includes other settings, such as ultrasounds provided in emergency departments, urgent cares, physician practices, and coincidental with other procedures (e.g., ultrasound guided biopsies, etc.). None of those ultrasounds would be reasonable to include in Duke's projected volume for this new IDTF facility. In any case, there is no analysis whatsoever to establish some meaning for this data or to show how it supports the need for the project. No evidence is provided to suggest that the projected number of procedures cannot be accommodated by existing providers, either in the service area or within a reasonable distance.

In short, Duke provides information regarding population growth for a service area it does not proposed to serve, and the utilization data it provides for the service area ZIP codes do not relate to the population growth projections. No analysis is given regarding the third-party data for the service component utilization and how, if at all, it supports the need for the proposed project.

DUHS Strategic Growth: The application points to the anticipated growth in its physician practices as support for the proposed project. As with the other information in the application, this section provides no nexus between the expected physician recruitment

goals and the need of patients in Orange County for a diagnostic center to provide mammography and ultrasound. In particular, the application references the more than 80 sites served by its physician practices and a recruitment target of 267 physicians, which would appear to be across all of those sites, without any discussion of recruitment impacting the proposed project. No information or analysis is provided to indicate that any of the recruitment targets include providers likely to refer to the proposed services, either based on their geography or their specialty. For example, the planned recruitment of a neurologist to the Wake Forest PDC clinic would have no obvious impact on referrals of patients from Orange County for the proposed services.

The application also refers to the letters of support for the project as an indication of the "strong support" for the project. Of note, the letters provide no information to support the need for the proposed project. Rather, the vast majority are form letters, which are understandably more convenient for physicians with active practices to sign; however, many of them specify their support for the ultrasound component without mentioning the need for mammography services. Even the primary care practice located at the same site as the proposed project has only a single letter, signed by one physician, which indicates support for addressing the perceived capacity constraints for ultrasound, while only briefly mentioning his practice of referring patients for mammography in accordance with national guidelines. One letter is from a pediatric practice and includes similar language regarding mammography referrals, which confirms the notion that this language is not specific to the intent of any particular supporting physician.

UNC Health understands that Duke intends to expand its physician network in the future. It also knows that form letters are often the most convenient way to obtain physician support for a project. However, these types of letters are simply insufficient to offset the lack of analysis in the application regarding the need for the proposed project, including the absence of any discussion as to how the proposed recruitment goals will drive the need in Orange County, as well as any indication by any physician that there is a lack of access to mammography services in particular.

Benefits of an IDTF: While there can be benefits of having lower cost options for outpatient care, these benefits do not support the need for the proposed project, given the existence of other non-HOPD providers in the service area and Duke's ability to convert its own HOPD facilities to IDTF status. The application states on page 24 that its existing imaging services "are all provided at hospital-based clinics and subject to provider-based charges and reimbursement." While this may be factually correct, it does not explain why Duke cannot pursue the conversion of these facilities to IDTF status. Of note, and as discussed in detail below, Duke has an existing clinic at Patterson Place, less than one mile from Orange County[1] and less than five miles from the proposed site. The application provides no discussion of this logical alternative, nor does it include any information regarding the capacity of the mammography equipment located there (see page 45), or why ultrasound equipment, which is obviously small and portable, cannot be added there, or why that facility should not be converted to IDTF status.

[1] The Durham/Orange County line is located just west of the I-40/15-501 interchange and Patterson Place is in the second block past the interchange on 15-501.

In short, the rationale in the application describes Duke's motivation for the project but fails to establish the need of the patients for a diagnostic center in Orange County with mammography and ultrasound services.

It should also be noted that the application inexplicably proposes to operate the mammography service only three days per week (page 25). Although Duke does not project sufficient utilization to need more than three days per week of coverage, the lack of full-time service also indicates a lack of actual need for the service. Notwithstanding these limited hours, Form H indicates that there will be more FTEs to provide the service (2.16 FTEs) compared to the ultrasound service (1.88 FTEs), the latter of which is proposed for five days per week. Given the limited hours of operation for the mammography service, as well as the available capacity within the service area (discussed below), Duke fails to provide any compelling evidence of the need of patients for the proposed project.

Finally, although the application repeatedly discusses the location of the proposed project in Orange County and the lack of a Duke imaging facility in Orange County, less than one-half of the identified patient population (48 percent) is from Orange County. The plurality, and perhaps the majority of patients come from Durham County, where Duke already has multiple outpatient sites that provide the same services, at least some of which can be converted to IDTF status. The clear and obvious better (and less costly) alternative would be to expand capacity, if needed, at an existing Duke site in Durham County, where such a significant portion of its patients originate, including more than one-half its existing patients that it proposes to shift to the proposed location, which would require them to travel outside of their home county for care. The patient need, particularly for Durham County patients, is simply not demonstrated in the application.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 7 and 18a.

4. Duke's utilization projections are unreasonable and unsupported.

Similar to other parts of the application, the utilization projections in Section Q lack sufficient supporting analysis and are not reasonable.

In Step 1, Duke refers to "its analysis of existing drive time patterns for ultrasound and screening mammography services" to support the identification of its primary service area and ultimately its projected utilization. The analysis it refers to is not included in the application, however, nor does Duke even attempt to summarize what that analysis shows. This analysis is essential to the Agency's review of the application, as it would enable the Agency to compare the proposed project with other facilities operated by Duke, their location, the location of other facilities in the area, the geographic and population size of the ZIP codes in the analysis of other facilities, among other factors. For example, ZIP code 27707, which is included in the proposed service area, also includes Duke's Patterson Place location, which provides mammography services (see page 45). An assessment of patients seeking mammography services at this location, both from the service area for the proposed facility as well as elsewhere, would inform the Agency regarding the reasonableness of the application's service area and in-migration

assumptions, and potentially its market share and utilization assumptions. Without this information, the application's assumptions cannot be evaluated for reasonableness.

In Step 2, Duke provides projected utilization for the proposed services from a third-party source. As noted above, the application fails to provide any assumptions for whether the ultrasound procedures are for all settings or just scheduled, outpatient cases as proposed in the application, but it would appear given the comparatively higher volume of these cases, that they include other settings, such as ultrasounds provided in emergency departments, urgent cares, physician practices, and coincidental with other procedures (e.g., ultrasound guided biopsies, etc.), which would not be provided in the proposed diagnostic center. Thus, the reasonableness of the projected utilization and whether it would be appropriate for the proposed project is not established in the application.

In Step 3, Duke projects utilization to "shift" from other Duke locations to the proposed facility. While this is not a novel approach to projecting utilization, the application makes several unreasonable assumptions. First, the application provides only eight months of actual data on which to base projected volume for the three project years. While the need to adjust for the impact of COVID-19 on historical utilization is explained, there is no evidence that the annualized 2020 volume for each of the service area ZIP codes can reasonably be assumed to remain the same through the third project year. Even though Duke certainly has historical data beyond the eight months of FY 2020 used in the application, no such data are provided to support the assumption that volume will be the same through the third year. Even if one assumes that the projected growth shown in Step 2 will occur for the service area, there is no historical data to demonstrate that Duke's volume from each ZIP code has remained flat or grown over the last few years; thus, this assumption is unsupported. Second, the application provides no information regarding the facilities that historically provided these procedures or whether the shift would occur uniformly across all existing facilities or if some would be impacted more than others. Third, no analysis or discussion is provided to support the various shift percentage projections, other than the notion that the largest shift will occur in the ZIP code of the proposed facility. There is no rationale, for example, of why the projected shifts are different for ultrasound and mammography, or why they are twice as high for mammography as for ultrasound. As noted above, there is no evidence in the application or the support letters of any issues with access to mammography services, so the reason that more patients would shift for this service is unexplained and irrational. The application also fails to explain why the shifts would be identical for all the other ZIP codes, no matter their distance from the proposed facility. As an existing provider with many other facilities, Duke has experience and data regarding volume shifts occurring when facilities are developed, yet these data were not provided in this application and these assumptions are unsupported.

In Step 4, Duke projects market share gains from the proposed project. While Duke does provide the reasons it believes its market share will increase, they do not sufficiently explain why it will increase or how it calculated the specific increases by ZIP code and modality. Specifically, even if one assumes the projected market utilization in Step 2 will occur, that does not mean that Duke will capture an increased share of this volume. As noted previously, Duke fails to provide information regarding the facilities at which it performed the utilization it projects to shift to the proposed facility; thus, it is not possible

to know whether the proposed facility will provide better access for these patients, some of whom were likely treated at facilities closer to home than the proposed facility (see discussion above). Further, the application provides no rationale to support the projected market share increase percentages, including why the projections are different for the two modalities. None of the discussion preceding the market share tables indicate that there is a difference in the impact of these factors on market share for one modality versus the other.

In Step 5, Duke projects an in-migration factor for the proposed facility. While it states that this is based on the in-migration at its Southpoint facility, that comparison is of no value without information regarding the service area definition it uses for that facility. For example, if Duke considers that facility to have a three-ZIP code service area with 13 percent of its patients coming from outside that area, then a 10 percent in-migration rate for the proposed project with a seven ZIP-code service area would not be reasonable. Once again, despite the fact that it is a large existing provider with a sophisticated data system, Duke fails to provide internal information to support the credibility of its assumptions and projections.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a.

5. Duke fails to demonstrate that it will not unnecessarily duplicate existing providers.

In Section G, the application notes some of the other providers that exist in the service area, including among others Wake Radiology Diagnostic Imaging and Duke's main campus, Southpoint clinic and Patterson Place clinic. Of note, two of these facilities are outpatient facilities located in the service area, Wake Radiology (ZIP code 27514, same as the proposed facility) and Duke's Patterson Place site (ZIP code 27707). The Wake Radiology facility is located at 110 S. Estes Drive, Chapel Hill, and is only four miles from the proposed site according to Google Maps. The Duke facility at Patterson Place is located on Highway 15-501, just east of I-40, and is only 4.6 miles from the proposed site according to Google Maps.

On page 6 of the application, the definitions provided by the Agency describe a service area as "the same as the projected patient origin reported in Section C, Question 3" for services like a diagnostic center for which there are no rules or *SMFP* definition of service area. Thus, the service area includes the seven ZIP codes defined in Section C.3, as well as other parts of Durham, Orange and other counties. Section G requires applicants to identify existing facilities providing the same service components in the service area, provide their historical utilization and explain why the proposed project will not unnecessarily duplicate those facilities. The application does provide some information for part of the service area, but inexplicably limits its analysis to facilities within 10-miles of ZIP code 27514, which is notably not a limitation it placed on its service area. The response is therefore insufficient based on the applicant's defined service area.

Moreover, the application fails to provide any analysis of the facilities it does identify in the application, including Duke's own facilities, or explain why the proposed project is needed despite the existence of these facilities. The application refers to population

growth in the Chapel Hill area; as noted above, the projected utilization for mammography services is expected to be lower than the population growth. The service area also expands significantly beyond Chapel Hill. Further, Duke's lack of imaging facilities in Orange County is not relevant to the analysis for three reasons: the service area extends well beyond Orange County, Duke does have existing facilities in the service area that provide the same services, and there are other existing facilities in the service area, including within Orange County that have capacity to provide additional mammography and ultrasound services.

The application provides no explanation as to why its existing Patterson Place facility, located in the service area, lacks sufficient capacity for mammography or why it cannot add ultrasound services. It also fails to address why it cannot convert to an IDTF or physician-based clinic, which would also provide lower, non-HOPD reimbursement. Without this analysis at a minimum, the application fails to demonstrate that it will not unnecessarily duplicate that and other Duke facilities. Additionally, Wake Radiology's existing facility in the same ZIP code as the proposed facility provides mammography and ultrasound services, along with numerous other imaging services, as noted on its website[2]. Wake Radiology is designated as a Breast Imaging Center of Excellence by the American College of Radiology, has available capacity to serve additional patients, and as also noted on its website, allows patients 40 and over to schedule a screening mammogram without a physician referral—or even as a walk-in without an appointment.

Wake Radiology's Chapel Hill facility provides screening and diagnostic mammography, as well as ultrasound (including venous doppler procedures). The facility provides screening mammography services five days per week and one Saturday per month; it can accommodate 55 patients for screening during the week and 14 on Saturdays. In FY 2019 (used instead of 2020 because data for the most recent year are lower due to the pandemic), Wake Radiology[3] performed at 45 percent of its capacity for screening mammography, as shown in the following table:

	Capacity
Monday-Friday	55/day x 5 days/week x 50 weeks/year = 13,750
Saturday (once per month)	14/day x 12 months = 168
Total	13,918
Screenings performed (FY 2019)	6,293
Utilization	**45.2%**
Available capacity	**7,625**

Of note, more recent data indicates growth from the 2019 volume; however, some of that growth may be attributable to the decompression of volume with the restart of elective procedures after the COVID-19 shutdown. In any case, Wake Radiology undoubtedly has

[2] https://www.wakerad.com/locations/chapel-hill/

[3] Wake Radiology provided UNC Health with its internal data for this analysis.

sufficient capacity to accommodate Duke's projected 2,342 screening mammography procedures, at a high-quality site with non-HOPD reimbursement.

Wake Radiology also provides ultrasound services. Considering just the breast ultrasounds provided at the facility, Wake Radiology performed 1,298 in 2019. Similar to mammography, Wake Radiology has capacity to provide additional ultrasounds to area residents with non-HOPD reimbursement.

Duke also failed to provide any analysis of its existing capacity in the service area, including on its main campus or at its Southpoint or Patterson Place locations. Considering the Patterson Place facility, which is its closest location to the proposed facility, Duke shows on page 45 that it provided 4,510 mammograms in 2019. At a minimum, that facility should be able to perform another 1,043 procedures, given the volume provided for the Southpoint facility (5,553 – 4,510 = 1,043). While it is reasonable to assume that the ultimate capacity is not 5,553, even assuming it is, the Patterson Place location should be able to accommodate all of the projected incremental mammography volume in Year 3. As shown in Section Q and reproduced below, Duke projects 1,040 procedures from incremental volume—the remainder are shifted from other locations or are in-migration.

Incremental Volume (due to Increase in Share)	393	714	1,040

Thus, the actual incremental volume—what Duke is not otherwise currently providing—can all be accommodated within the service area (ZIP code 27707), less than five miles from the proposed site. If Duke believes it is better for patients, it can choose to reorganize its existing HOPD site as an IDTF without any capital expenditure.

The application's failure to provide any analysis of these existing facilities, particularly its own facilities located in the service area, is a factor that the Agency has found to be insufficient to demonstrate conformity with various review criteria in multiple past reviews. A few examples of similar diagnostic center proposals that were denied are provided below.

- Project ID # M-8022-07 – Scotland Imaging, LLC – proposal to acquire x-ray equipment with computed radiography to replace existing x-ray machine and computed radiography equipment, thereby creating a diagnostic center.

  Regarding Criterion 3, the Agency found: "*In this application, the applicant made no mention of, nor attempt to secure information from Hamlet Hospital, in the proposed service area. Further, it is possible to obtain a list of other diagnostic imaging providers in the service area and the specific pieces of equipment each one owns. The NC Department of Environment and Natural Resources, North Carolina Radiation Protection Section does maintain a list of providers and the types of diagnostic equipment each provider registers and owns. Furthermore, the applicant made no attempt to demonstrate the utilization of the radiographic equipment at the health service facilities in the defined service area were operating at 80% of the maximum capacity. In addition, the applicant did not*

adequately examine other providers of the proposed service in the service area, such as Hamlet Hospital. Further, the applicant did not adequately demonstrate that it attempted to project utilization of any existing and approved medical diagnostic equipment in its proposed service area. In summary, the applicant did not adequately document the need for the replacement x-ray machine and computed radiography (CR) unit requested in this application. Consequently, the application is not conforming to this criterion." *See* Findings, pages 7-8 [emphasis added].

Regarding Criterion 6, the Agency noted: "*The applicant did not adequately demonstrate the need for the proposed diagnostic equipment, and consequently the establishment of a diagnostic center. Thus, the applicant did not adequately demonstrate that the proposed equipment would not result in the unnecessary duplication of existing diagnostic services or facilities in Scotland County*." *See* Findings, page 9.

- Project ID # G-8086-08 – Mountainview Imaging, LLC – proposal to acquire one CT scanner, one digital Mammography unit, one Ultrasound unit, and one digital X-ray unit, and establish a new diagnostic center to be located on Mountainview Road in King.

  Regarding Criterion 3, the Agency determined:

  "*However, the applicant failed to include, in its utilization, its own mobile mammography unit which the applicant states on page 65 of the application that the mobile mammography unit currently serves Mountainview Medical Associates. In addition, the applicant's market share assumptions do not take into account the Stokes Medical Center Park (SMCP), located at 167 S. Moore Road in King and less than two tenths of a mile from Mountainview Medical Associates and the proposed location of MI. Stokes Medical Center Park currently offers mammography and general radiology services. However, the applicant fails to account for the mammography services offered at SMCP, just down the street, and fails to reasonably explain why patients would shift to MI rather than stay at SMCP. In addition, the applicant states in Step 2, page 77, that there is only one provider of mammography screening in the defined service area, that is designated as a "health service facility, as that term is defined in the CON statute." While SRMC is the only other "health service facility," there are other outpatient imaging clinics, such as the Breast Clinic, that serves patients from the service area*." *See* Findings, page 29.

  "*Moreover, the applicant fails to discuss the X-Ray machines at Pilot Mountain Family Practice and Mountain View Medical Associates, both practices are a Novant Medical Group physician practices. While this data is not available to the public, it is available to the applicant. Thus, although the applicant had utilization projections for the defined service area, the projections are based on unidentified facilities in unidentified counties*." *See* Findings, page 33.

"*In summary, the applicant's assumption that the placement of digital X-ray equipment into the service area, less than three miles from existing comparable equipment, is unreasonable. Furthermore, the applicant's projections demonstrate the need for three X-ray machines. However, the defined service area already has three X-ray machines…Consequently, the applicant did not adequately demonstrate that projected utilization of the proposed X-ray equipment in the defined service area is based on reasonable and supported assumptions. Therefore, the applicant failed to adequately demonstrate a need for additional X-ray equipment in Stokes County*." *See* Findings, page 34.

- Project ID # J-8248-08 – Wake Radiology Services, LLC NWRO – proposal to acquire a full-field digital mammography system to replace existing analog film-screen mammography equipment, thereby creating a diagnostic center.

  Regarding Criterion 3, the Agency noted: "*The applicant projected the utilization of its own equipment at the NWRO location, but failed to take into account the projected utilization of the other digital mammography units in the service area. The North Carolina State Office of Budget and Management provides a list of diagnostic imaging equipment in the state, but does not provide utilization information; therefore, utilization of other providers' equipment may be difficult to project. However, Wake Radiology Services, LLC owns many facilities in Wake County that provide digital screening mammography and, thus, the applicant could have projected capacity of the other digital mammography units in the proposed service area that it owns and/or operates. Further, the applicant's projections of the number of screening digital mammography procedures to be performed are unreliable and unreasonable*." *See* Findings, page 18.

- Project ID # J-10025-12 – Durham Diagnostic Imaging d/b/a NCDI-Cary – proposal to develop a new diagnostic center by acquiring one ultrasound unit for existing outpatient imaging center.

  Under Criterion 3, the Agency found:

  "*Moreover, in comments submitted during the public comment period, Wake Radiology provided utilization for the ultrasound at Wake Radiology-Cary (located in zip code 27518) and indicated that the ultrasound operates far below 80% of capacity, as defined by Wake Radiology (43% of capacity for CY2011 and 44% for CY2012). Novant Health owned, MedQuest managed North Carolina Diagnostic Imaging-Holly Springs (NCDI-Holly Springs) received a certificate of need (Project ID # J-8537-10) in June 2011 to develop a diagnostic center with an ultrasound unit to be located in the Holly Springs zip code of 27540…The applicant should be able to determine the annual capacity and to project utilization for that unit since it will be owned ultimately by Novant and managed by MedQuest which is owned by Novant*." *See* Findings, page 8.

- Project ID # F-10056-12 – Mecklenburg Diagnostic Imaging d/b/a PIC-Mooresville – proposal to develop a new diagnostic center by acquiring a mammography unit for an existing imaging center.

  Regarding Criterion 3, the Agency found: "*<u>However, according to comments submitted by LNRMC during the written comment period, the applicant underestimated LNRMC's capacity based on faulty assumptions</u>. LNRMC states it offers mammography services from 8 AM to 5 PM, Monday through Friday and can serve as many as four patients per hour. Therefore LNRMC's capacity is 9,180 procedures per unit (9 hours per day x 255 days x 4 patients per hour = 9,180) and it operated at only 39% of capacity (3,548 / 9,180 = 38.64%) during FFY 2011. See* Findings, page 11 [<u>emphasis added</u>].

  Under Criterion 6, the Agency found: "*Information on utilization of existing mammography equipment is not publicly available such that it is possible to determine if excess capacity exists in the proposed service area. The exception is when the mammography equipment is owned and operated by a hospital, in which case, the utilization is reported on its hospital license renewal application. LNRMC reported performing 10,643 procedures (3,548 per unit) on three mammography units during FFY 2011. In Section II, pages 27-28, the applicant provided the assumptions it used to determine that LNRMC's mammography units operated at 89.7% of capacity. Those assumptions are: 7.75 hours per day x 255 days x 2 patients per hour = 3,952 procedures per unit [3,548 / 3,952 = 89.7%]. However, according to comments submitted by LNRMC during the written comment period, the applicant underestimated LNRMC's capacity based on faulty assumptions. LNRMC states it offers mammography services from 8 AM to 5 PM, Monday through Friday and can serve as many as four patients per hour. Therefore LNRMC's capacity is 9,180 procedures per unit (9 hours per day x 255 days x 4 patients per hour = 9,180) and it operated at only 39% of capacity [3,548 / 9,180 = 38.64%] during FFY 2011*." *See* Findings, page 15.

Although each review is unique, it is clear from these Agency Findings that the Agency does consider information from other existing providers in the service area relevant to its review and analysis under Criteria 3 and 6, and that applicants are required to analyze data for their own facilities at a minimum.

Based on this information, the proposed project would clearly result in unnecessary duplication of the proposed services. **The application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a.**

6. <u>The application fails to demonstrate the feasibility of the project, based on reasonable projections of costs and charges</u>.

   In the assumptions for Form F.2 for ultrasound, Duke states that reimbursement for commercial and self-pay patients was based on "DUHS actual reimbursement for services at Duke University Hospital outpatient imaging department at Southpoint Ultrasound…." As Duke discusses in the application, reimbursement for HOPD is higher for the proposed

services than IDTF reimbursement. Therefore, by using the HOPD reimbursement for these payors, Duke has overstated its revenue for the proposed service. Given the thin margin for the proposed project (net income of only $72,000 in Year 3), and since ultrasound is projected to be the only profitable service component, the overstatement of ultrasound revenue is a significant issue. As a result, the Duke Application fails to show the financial feasibility of its project.

In addition, the application fails to provide any assumptions or otherwise document the basis of the "rental expense" for the project, which is presumably the lease for the proposed facility. The assumptions for the financial pro formas do not discuss this expense, and the lease provided in Exhibit K.4 provides no financial terms for the lease. As such, the basis and reasonableness of this expense is absent from the application.

Based on these issues, the application should be found non-conforming with Criterion 5.