

August 12, 2016

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RE: Novant Health, Inc. Comments in Opposition to Charlotte Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) Petition to Remove the Need Determination for One Fixed MRI Scanner in Lincoln County from the 2017 State Medical Facilities Plan

Dear Ms. Bennett:

Attached are Novant Health Inc.'s Comments in Opposition to the above CHS petition regarding the 2017 SMFP Need Determination for one new fixed MRI scanner in Lincoln County.

Please do not hesitate to contact Barb Freedy or Tiffany Brooks if you have questions.

Sincerely,

A handwritten signature in blue ink that reads "Barbara L. Freedy".

Barbara L. Freedy, Director CON
Novant Health, Inc.

A handwritten signature in blue ink that reads "Tiffany Brooks".

Tiffany Brooks, Manager CON
MedQuest Associates

August 12, 2016

Paige Bennett, Assistant Section Chief
Healthcare Planning Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) Petition to Remove the Need Determination for One Fixed MRI Scanner in Lincoln County from the 2017 State Medical Facilities Plan – Novant Health, Inc. Comments in Opposition

Dear Ms. Bennett:

Novant Health, Inc. submits the following comments in opposition to the petition submitted by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) to remove the need determination for one fixed MRI scanner in Lincoln County from the 2017 State Medical Facilities Plan (SMFP). CHS's hospital in Lincoln County, Carolinas Healthcare System-Lincoln (CHS-Lincoln) is the sole provider of fixed MRI services in Lincoln County. Novant Health provides both fixed and mobile MRI services in Health Service Area (HSA) III, where Lincoln County is located. The MRI need methodology has previously triggered a need determination for Lincoln County in the draft 2015 and draft 2016 SMFPs. Each time, CHS has successfully petitioned to remove the need determination from the SMFP; however, there has never been any opposition to the CHS petitions. There is again a need determination in the draft 2017 SMFP for an additional fixed MRI scanner in Lincoln County, and again CHS has petitioned to have that need determination removed.

As the historical MRI volume demonstrates, Lincoln County continues to experience positive growth for MRI services coupled with significant outmigration of Lincoln County residents seeking MRI services in other counties. Contrary to CHS's position that no need exists in Lincoln County for an additional fixed MRI scanner, it appears that Lincoln County residents could benefit from the availability of an additional fixed MRI scanner in order to enhance competition and improve geographic and financial accessibility to MRI services.

Background

Lincoln County is located in Health Service Area III and has approximately 81,417 residents. The median household income from 2010-2014 was \$48,664. Population data for Lincoln

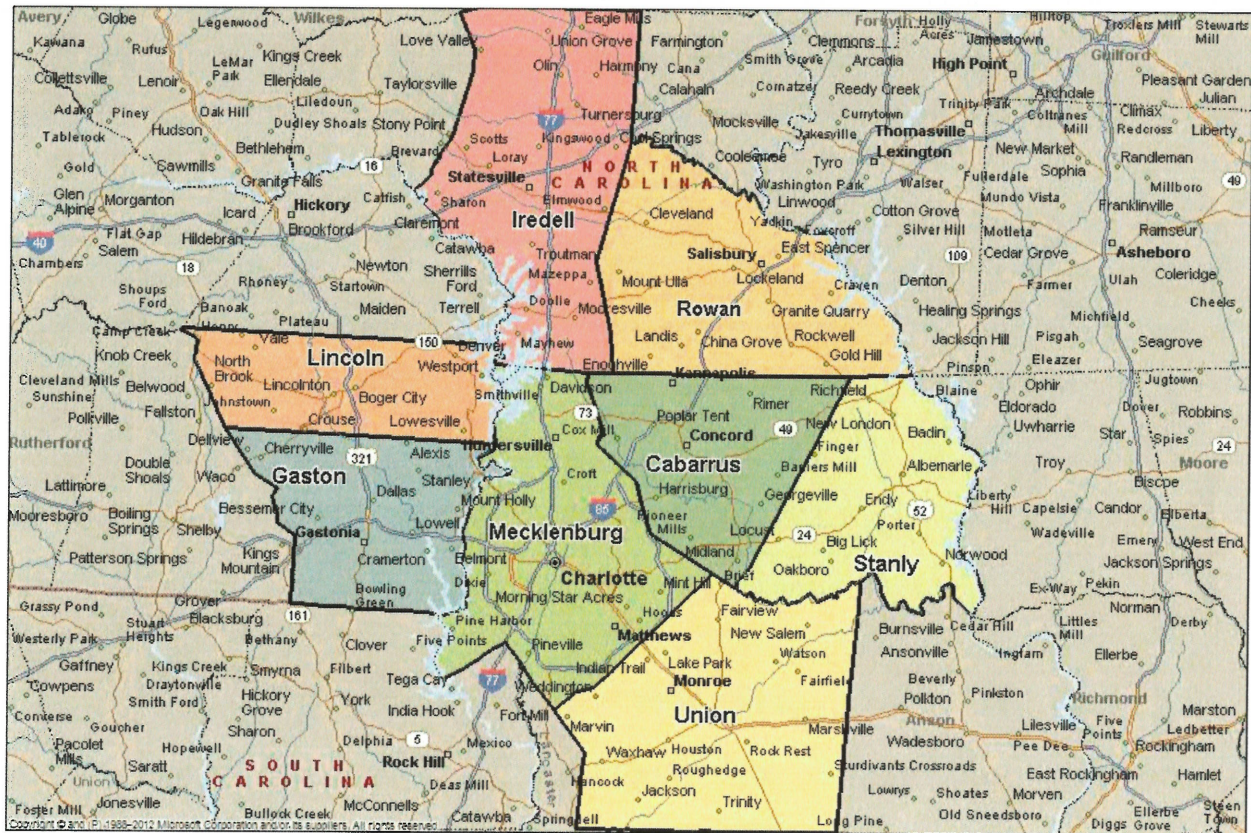
County is provided below, which indicates positive annual growth for this service area. It should be noted that the 65+ population in Lincoln County is growing at a very robust rate. Typically, patients in this age group rely more heavily on healthcare services and local accessibility along with affordability is a critical factor.

Year	2015	2016	2017	2018	2019	2020
Lincoln County	80,810	81,417	82,026	82,634	83,243	83,849
% Change	---	0.75%	0.75%	0.74%	0.74%	0.73%
65+	13,094	13,616	14,108	14,592	15,125	15,683
% Change	---	3.99%	3.61%	3.43%	3.65%	3.69%

Source: Office of State Budget & Management

Currently, Lincoln County only has one provider of MRI services, CHS-Lincoln, which operates a fixed MRI scanner. The most recent data (10/1/2014-9/30/2015) indicates that CHS-Lincoln performed 3,904 unweighted scans with a weighted MRI volume of 4,952 scans. The threshold to trigger a new MRI scanner is 3,775 weighted scans for a service area with one fixed MRI scanner. Based on FFY 2015 data, CHS-Lincoln’s sole fixed MRI scanner is operating at 131% of the need threshold. Clearly, there is a need for additional MRI capacity in Lincoln County.

Health Service Area III



CHS Petition

CHS has filed petitions with the State Health Coordinating Council in 2014 and 2015 (for the draft 2015 and draft 2016 SMFPs) to remove the need determination for one fixed MRI scanner in Lincoln County. The draft 2017 SMFP is the third time in three years that there has been a need determination for an additional fixed MRI scanner in Lincoln County. CHS's position has been that it is the sole provider of MRI services in the county and it does not believe a need exists for an additional MRI scanner based upon the volume at CMC-Lincoln. CHS states that it supports the current need methodology for fixed MRI scanners in the SMFP, which unquestionably shows a need for an additional MRI scanner in Lincoln County, but then proceeds to ask that need determination be deleted. See 2016 Petition, page 1. The two positions cannot be reconciled. If CHS supports the need methodology, then it should not be asking to have the need determination removed. The fact that CHS does not think that it would be able to file a successful CON application to develop a second fixed MRI scanner in Lincoln County, see 2016 Petition, page 2, is not a "unique or special attribute of a particular geographic area or institution" that warrants an adjustment in the need determination. See 2016 SMFP, page 9. The petition assumes, incorrectly, that a new entrant could not gain CON approval "without simply shifting volume from an existing provider and thereby resulting in underutilized scanners in Lincoln County." See 2016 Petition, page 2, fn1. CHS's speculative statement is just another way of saying that CHS does not want competition from a new entrant. It should not be left to the sole provider of a service in a county to decide what the population does or does not need, particularly where the data consistently show year after year that there is a genuine need for additional MRI capacity in Lincoln County.

In previous petitions CHS has also referenced the slow or flat North Carolina growth rate in MRI volume. There has been no opposition in the past and the petitions have been approved. Notably, CHS did not include the argument in this year's Petition that North Carolina MRI volume growth is slow, flat, or decreasing. In fact, overall MRI growth in North Carolina has increased 4.2% annually since 2013, and increased over 5% from 2014-2015 as shown in the following table:

	2013	2014	2015	CAGR 2013- 2015	AGR 2014- 2015
MRI Scans	777,633	800,182	843,768	4.2%	5.4%

Source: SMFPs

In addition, MRI use rates in North Carolina have increased annually since 2013 as shown in the following table:

North Carolina MRI Use Rates

	2013	2014	2015
MRI Scans	777,633	800,182	843,768
Population	9,860,149	9,953,687	10,054,722
Use Rate	78.866	80.391	83.918

Source: SMFPs; NC OSBM

Based on the data presented in the CHS petition, the volume at CHS-Lincoln has experienced positive growth in demand each year since FFY 2010. See the following chart from the CHS Petition:

Historical Weighted MRI Scans								
	FFY 2010	FFY 2011	FFY 2012	FFY 2013	FFY 2014	FFY 2015	% Change 10-15	CAGR 10-15
CHS-Lincoln	2264	2978	3497	3860	4667	4952	118.7%	16.9%
Blue Ridge Radiology	758	851	338	0	0	0	-100%	-100%
Lincoln Co. Total	3022	3829	3835	3860	4667	4952	63.9%	10.4%
Annual % Change		26.7%	0.2%	0.7%	20.9%	6.1%		

From CHS Petition, page 2 – 7/28/2016 for the 2017 SMFP

CHS cites MRI patient origin data from the Division of Health Service Regulation (DHSR) which indicates that the total number of Lincoln County residents that obtained MRI scans was 5,804 patients during FFY 2015. Based on this information, Lincoln County residents have a very high out-migration percentage for MRI services as 64% of patients obtain MRI services in other counties. Notably, more than 31% of Lincoln County MRI patients obtain MRI services in Mecklenburg County, which shares a border with Lincoln County. As shown in CHS's Petition:

Lincoln County – Patient Origin

Service Location	Patients	% of Total
Lincoln	2,087	36.0%
Mecklenburg	1,825	31.4%
Catawba	707	12.2%
Gaston	662	11.4%
Iredell	179	3.1%
Forsyth	84	1.4%
Burke	67	1.2%
Cabarrus	65	1.1%
Cleveland	57	1.0%
All other NC Counties	71	1.2%
Total	5,804	100%

From CHS Petition, page 3 – 7/28/2016 for the 2017 SMFP

Novant Health reviewed the patient origin data for service areas with one fixed MRI scanner. Of the 25 service areas that fall into this category, Lincoln County had the 7th highest level of outmigration and the highest total weighted MRI volume. With such a high outmigration rate, it would appear that, despite CHS's claims that there is no backlog at CHS-Lincoln, accessibility is an issue in Lincoln County. See Attachment A for the MRI patient origin chart. Giving Lincoln County residents another in-county option to receive MRI scans may help reduce this outmigration and save Lincoln County residents time and money.

Novant Health – MRI Service to Lincoln County Patients

Based on internal data, Novant Health facilities (both hospitals and outpatient imaging centers) provided MRI services to nearly 1,000 Lincoln County residents during CY 2015. The number of Lincoln County patients utilizing Novant Health outpatient imaging sites is expected to increase by over 18% from CY 2015 to CY 2016. Novant Health does not currently operate fixed or mobile MRI services in Lincoln County but does offer MRI services in Mecklenburg, Gaston, Iredell, Union, Rowan and Cabarrus Counties. According to the data from DHSR regarding patient origin, Novant Health is providing service to just over 17% of Lincoln County MRI patients despite not having any MRI service located within Lincoln County.

Novant Health anticipates that its presence will continue to grow in Lincoln County based on patient demand. Novant Health Medical Group currently operates two medical practices in Lincoln County in the Denver area, which is located near Lake Norman. Novant Health is evaluating plans to further increase accessibility to care for its patients in the Lincoln County area.

Analysis

One of CHS’s primary reasons for requesting the elimination of the need determination in Lincoln County “is the unlikely possibility that an applicant for a second MRI scanner in Lincoln County could meet the required CON performance standards with reasonable utilization assumptions.” See Petition, page 2. This statement is written from the perspective that only CHS can (or would) apply to develop the needed MRI scanner. CHS's supposition is wrong for two reasons: (1) there may be other potential applicants, such as Novant Health; and (2) regardless of whether CHS considers itself a viable applicant, data provided by CHS in the Petition provides sufficient documentation to justify a need for an additional MRI scanner in Lincoln County using a variety of methodologies.

Need Analysis Based upon Historical Growth

As discussed in the CHS Petition, MRI CAGR in Lincoln County has been over 10% since 2010. The following table analyzes the CAGR on a continuing year to year basis using the five-year trend provided in the CHS:

	CAGR 2010- 2015	CAGR 2011- 2015	CAGR 2012- 2015	CAGR 2013- 2015	AGR 2014- 2015
MRI Volume @ Lincoln County Providers	10.4%	6.6%	8.9%	13.3%	6.1%

Source: CHS Petition, page 2

As shown in the previous table, MRI volume in Lincoln County is increasing and continues to increase at very significant rates. Further, it should be noted that CHS did not provide any year to date data for FFY 2016 for Lincoln County to illustrate growth in FFY 2016. Projecting future MRI volume in Lincoln County using only the historical Lincoln County CAGR results in a need for 2.6 additional MRI scanners as shown in the following table.

Projected Lincoln County Weighted MRI – 10.4% CAGR

	Projected Weighted						
	2016	2017	2018	2019	2020	2021	2022
MRI Volume @ Lincoln County Providers	5466	6034	6660	7351	8115	8957	9887
CAGR	10.4%	10.4%	10.4%	10.4%	10.4%	10.4%	10.4%
MRI Need @ 3,775 per MRI Scanner							2.619053

Note that this analysis does not take into account any change in out-migration, which would occur if a new freestanding fixed MRI provider entered the market.

While it is improbable that volume will continue to grow at 10.4%, using half this growth rate, which is comparable to the North Carolina annual growth rate of 5.4%, and less than actual growth in Lincoln County from 2014-2015, also results in a need for an additional MRI scanner in Lincoln County when out-migration is decreased by as little as 10% as shown in the following table:

Projected Lincoln County Weighted MRI – 5.2% CAGR

	2016	2017	2018	2019	2020	2021	2022
MRI Volume @ Lincoln County Providers	5209	5479	5764	6063	6378	6709	7057
CAGR	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%
Recapture 10% 2015 Market Share							696
Combined							7754
MRI Need @ 3,775 per MRI Scanner							2.05

The above methodology is based upon reasonable assumptions and justifies a need for an additional MRI scanner in Lincoln County. The fact that the data clearly show a need for an additional fixed MRI scanner rebuts CHS's stated concerns about "unnecessary duplication." See Petition, page 4.

Need Analysis Based upon Use Rate Analysis

Using historical CAGR to project future volume is only one of many ways to project the need for and expanded MRI service in Lincoln County. A use rate analysis takes into consideration many different variables. This methodology can address issues such as: an access problem in the County; or disease incidence and prevalence that might be greater than the state average. These are a few of the many factors that would be discussed in a CON MRI Application review. Calculating need based upon North Carolina MRI use rates and decreased out-migration also results in a need for a second MRI scanner in Lincoln County.

Beneficial Choice and Competition

Leaving the MRI need determination for Lincoln County in the 2017 SMFP will potentially offer a new option for a fixed MRI provider in Lincoln County and more choices for physicians and their patients. It may reduce the outmigration for MRI services that now occurs for Lincoln County residents, thereby saving them time and money. A new fixed MRI provider will also promote beneficial competition and choice in Lincoln County. Competition can be a useful tool in expanding local access to services, promoting cost effectiveness by putting downward

pressure on costs of care, and encouraging high quality, efficient care. By contrast, not allowing Lincoln County residents to have a choice of fixed MRI providers in Lincoln County – when the data clearly demonstrates the need for additional service – harms their interests and the health planning process generally. Among other things, it inhibits access and leads to higher prices. Access is an important consideration, not only geographically, but also financially. Having another provider in Lincoln County may enhance the ability of all residents of Lincoln County, regardless of their ability to pay, to receive care.

The competition offered by a second fixed MRI scanner in Lincoln County is perfectly consistent with the SMFP Basic Principles of quality, access and value. Competition drives providers to improve their quality. Access, which appears to be a serious issue in Lincoln County as evidenced by the significant outmigration, will be enhanced. Competition adds value as it can lead to lower prices and greater efficiencies.

Prior Petitions to Remove a Proposed SMFP Need Determination Using and Adjusted Need Determination Petition

Novant Health is unaware of a situation where an existing provider has petitioned to zero out the need and the SHCC has approved that petition when another provider has commented against zeroing out a need. Several petitions to zero out the need have been approved; with no comments in opposition, including the following.

- New Hanover Regional Medical Center petitioned to zero out a need for cardiac catheterization several years in a row. No one objected to these petitions.
- Cape Fear Valley Health System petitioned to zero out the need for additional acute care beds in 2014 and 2015. No one objected to these petitions.
- CHS has petitioned for several years to zero out the MRI need in Lincoln County. Until now, no one has objected to these petitions.

Conclusion

As an existing provider of MRI services in HSA III, Novant Health supports the need for an additional fixed MRI scanner in Lincoln County in order to enhance accessibility and promote competition. The MRI need methodology has generated a need determination for Lincoln County in the last three planning cycles, which have been eliminated each time. Many factors exist that support the inclusion of the MRI Scanner need determination for Lincoln County in the 2017 SMFP. There is a substantial amount of outmigration for Lincoln County MRI patients, which should be an important concern for members of the State Health Coordinating Council. The MRI volume in Lincoln County continues to escalate each year. The population of Lincoln County continues to grow each year, particularly the 65+ population. As the sole existing MRI

provider in Lincoln County, CHS has failed to demonstrate that any “unique or special attributes of a particular geographic area or institution” exist in Lincoln County pertaining to fixed MRI services. The need determination should remain in the 2017 SMFP and any applicant should be given the rightful opportunity to demonstrate need for a new fixed MRI scanner in Lincoln County in accordance with the Certificate of Need law, including CON statutory review criteria.

There is sufficient evidence to indicate that there is a need for an additional MRI in Lincoln County and the SHCC should deny this Petition.

File: Lincoln County – Opposition to Petition FINAL 8-12-16.docx

ATTACHMENT A

MRI Patient Origin Data – North Carolina Counties with One Fixed MRI Scanner

County	Outmigration Percentage – MRI Patient Origin Report	Service Area Total Weighted MRI Volume – Draft 2017 SMFP
Richmond	91.95%	2536
Franklin	88.2%	657
Person	80.87%	811
Granville	80.16%	1525
McDowell	71.22%	1045
Edgecombe	64.79%	2257
Lincoln	64.04%	4952
Lee	62.96%	3060
Halifax	61.22%	2467
Stanly	61.15%	3022
Sampson	58.14%	2487
Beaufort	56.25%	2242
Ashe	55.6%	1041
Wilkes	53.6%	3109
Caldwell	52.8%	4123
Lenoir	49.61%	3275
Columbus	46.5%	3419
Rutherford	45.46%	2990
Mitchell	41.34%	1470
Transylvania	37.56%	2440
Hertford	30.63%	2207
Chowan	27.4%	2181
Cherokee	25.14%	2121
Dare	16.76%	2235
Pasquotank	10.33%	3304

Source: Department of Health Service Regulation for MRI Patient Origin Report 2015 and Table 9P from the 2017 Draft SMFP