

Competitive Comments on Mecklenburg County MRI Applications

submitted by

Mercy Hospital, Inc. d/b/a Carolinas HealthCare System Pineville

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Mercy Hospital, Inc.¹ d/b/a Carolinas Healthcare System Pineville (CHS Pineville) submits the following comments related to Novant Health Presbyterian Medical Center's (NH Presbyterian) application to acquire a fixed MRI scanner in Mecklenburg County. CHS Pineville's comments 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). In order to facilitate the Agency's ease in reviewing the comments, CHS Pineville has organized its discussion by issue, specifically noting the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the NH Presbyterian application, Project ID # F-11433-17. The following comments include general comments on NH Presbyterian's application as well as application-specific comments and a comparative analysis related to CHS Pineville's application to acquire a fixed MRI scanner, Project ID # F-11425-17. Based on the following comments, it is clear that NH Presbyterian's application should be denied.

GENERAL COMMENTS

The *2017 SMFP* identifies a need for an additional fixed MRI scanner in Mecklenburg County which is most heavily influenced by the MRI utilization of CHS Pineville and its related entities². As shown below in a table excerpted from page 41 of CHS Pineville's application, Carolinas HealthCare System's (CHS) and Carolinas Imaging Services' (CIS) fixed MRI scanners have the highest weighted average MRI utilization per fixed magnet among all providers in Mecklenburg County. By contrast, Novant Health's fixed MRI scanners (which includes NH Presbyterian) have the lowest weighted average MRI utilization per fixed magnet in the county. Please note that the table below includes the following approved, but not yet operational scanners:

- Novant Health Matthews Medical Center (NH Matthews) per Project ID # F-8688-11
- The conversion of Project ID # F-8327-08 to a fixed MRI at Novant Health Huntersville Medical Center (NH Huntersville)
- OrthoCarolina Ballantyne per Project ID # F-10287-14
- CIS-Huntersville per Project ID # F-11182-16

¹ Mercy Hospital, Inc. owns CHS Pineville. As explained in the CHS Pineville application, Mercy Hospital, Inc. is wholly owned by Mercy Health Services, Inc., which is wholly owned by The Charlotte-Mecklenburg Hospital Authority (CMHA) d/b/a Carolinas HealthCare System (CHS).

² Carolinas Imaging Services (CIS) is a joint venture of CHS and Charlotte Radiology. Both CHS and CIS own existing fixed MRI scanners in Mecklenburg County.

FFY 2016 Fixed MRI Utilization: Ranking by Weighted Procedures per Fixed Magnet

Rank	Provider	Weighted Procedures	Fixed Magnets	Weighted Procedures per Fixed Magnet
	CHS Pineville	10,485	1	10,485
	Carolinas Medical Center (CMC)/ Carolinas Medical Center-Mercy	30,304	5	6,061
	CHS University	5,849	1	5,849
	CIS-Ballantyne	3,922	1	3,922
	CIS-SouthPark	3,769	1	3,769
	CIS-Huntersville	0	1	0
#1	CHS/CIS Total	54,330	10	5,433
#2	CNSA Total	4,385	1	4,385
	OrthoCarolina Spine	8,591	1	8,591
	OrthoCarolina Ballantyne	0	1	0
#3	OrthoCarolina Total	8,591	2	4,296
	NH Presbyterian	15,157	3	5,052
	NH SouthPark	3,857	1	3,857
	NH Huntersville	7,691	2	3,846
	NH Matthews	7,537	2	3,769
	NH Ballantyne	2,691	1	2,691
	NH Museum	2,796	1	2,796
#4	Novant Health Total	39,728	10	3,973

Note: Excludes specialized MRI units such as dedicated pediatric and dedicated breast scanners consistent with their exclusion from the MRI need methodology in the SMFP.

Source: *Proposed 2018 SMFP* and corrected CHS data. See Exhibit C.4 of CHS Pineville application.

Of CHS and CIS’s fixed MRI scanners, CHS Pineville’s is the most highly utilized. In fact, CHS Pineville’s fixed MRI scanner is the most highly utilized fixed MRI scanner in the state and has been so for the last three years, as shown in its application. Moreover, CHS Pineville performed more than twice as many scans on average per fixed unit than NH Presbyterian.

In its application, NH Presbyterian states that it needs additional MRI capacity based on its high utilization and the resulting impact on patient care. For example, NH Presbyterian states that “[f]rom July 1, 2016 to June 30, 2017, the two existing fixed MRI scanners at [NH Presbyterian’s] main campus performed a total of 12,573 weighted MRI procedures, or an average of 6,286 per fixed scanner . . . Without additional fixed MRI capacity to address the ongoing demands . . . [NH Presbyterian] will be faced with a critical access issue for MRI services.” Over the most recent 12 month period, CHS Pineville performed 9,894 weighted MRI procedures on one fixed MRI unit (see page 62 of its application), well in excess of NH Presbyterian’s utilization. NH Presbyterian states that its “fixed MRI scanners operate seven days per week, two shifts per day beginning at 7am until at least 11pm in an effort to keep pace with the high demand” (page 39). CHS Pineville’s current hours of operation for MRI services are from 7:00 am to 2:00 am Monday through Friday and 7:00 am to 7:00 pm on Saturday and Sunday. Even with these extended hours of operation, CHS Pineville is faced with the need to supplement with contracted mobile MRI services each Monday and every other Wednesday. Letters of support for NH Presbyterian

state that its MRI utilization “creates a bottleneck for physicians and patients seeking to access MRI diagnostic studies.” Given that CHS Pineville’s MRI utilization is considerably higher than NH Presbyterian’s, it faces even greater patient care issues. CHS Pineville states in its application that “there are significant inconveniences, costs, and inefficiencies for patients, physicians, staff, and the healthcare system as a whole resulting from the demand for CHS Pineville’s MRI dramatically outpacing its capacity. CHS Pineville’s MRI capacity issues result in long wait times and unnecessary and expensive additional time in the hospital. These MRI procedures are needed to diagnose illness and to develop treatment plans to improve the health of patients. The delays that result from equipment operating far above its optimal capacity also delay the diagnosis, treatment, recovery, and return to normal life for patients” (pages 52-53).

Overall, CHS/CIS is the only provider that could meet the planning target for one additional fixed MRI scanner today (above and beyond approved but not yet operational fixed scanners), as shown below from a table excerpted from page 43 of the CHS Pineville application.

**FFY 2016 Fixed and Mobile MRI Utilization:
Ranking by Weighted Procedures above Threshold**

Rank	Provider	Weighted Procedures	Fixed Equivalent Magnets	Threshold Based on 4,805 Procedures per Unit	Weighted Procedures Above Threshold
#1	CHS/CIS	58,746	10.81	51,942	6,804
#2	Mecklenburg Neurological Associates	1,961	0.34	1,634	327
#3	CNSA	10,422	2.15	10,331	91
#4	OrthoCarolina	18,237	3.95	18,980	-743
#5	Novant Health	42,572	10.53	50,597	-8,024

Note: Excludes specialized MRI units such as dedicated pediatric and dedicated breast scanners consistent with their exclusion from the MRI need methodology in the SMFP.

Source: Proposed 2018 SMFP and corrected CHS data. See Exhibit C.4 of CHS Pineville application.

As shown in the table above, CHS and CIS’s fixed and mobile MRI scanners performed 6,804 procedures above their target utilization, well above the planning threshold for one additional scanner, 4,805 procedures. By contrast, Novant Health’s fixed and mobile scanners operate at more than 8,000 procedures below their target utilization. These analyses show that CHS Pineville, specifically, and CHS/CIS, in total, currently demonstrate the greatest need for additional fixed MRI capacity in Mecklenburg County whereas Novant Health demonstrates a surplus of capacity.

APPLICATION-SPECIFIC COMMENTS

NH Presbyterian’s application to acquire a fixed MRI scanner should not be approved as proposed. CHS identified the following specific issues, each of which contributes to NH Presbyterian’s non-conformity:

- (1) Failure to provide assumptions or methodology for utilization projections**
- (2) Failure to include all capital costs**
- (3) Failure to demonstrate financial feasibility**

Each of the issues listed above is discussed in turn below. Please note that relative to each issue, CHS has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

Failure to provide assumptions or methodology for utilization projections

NH Presbyterian’s application does not include a methodology or assumptions for the projected MRI utilization at its facility or for the projected MRI utilization for any of its related entities. NH Presbyterian completed Form C Utilization, but provides no demonstration of how its utilization was determined. Moreover, NH Presbyterian’s application does not include the projected utilization for any of its related entities.

In Section Q, on pages 122 and 123 (in the original copy submitted to the Healthcare Planning and Certificate of Need Section), NH Presbyterian states its projected weighted and unweighted MRI procedures for the interim period prior to development of the project, but does not discuss how it determined that projected utilization, as shown in the excerpt below:

Form C - Utilization Assumptions:

- 1. As requested, the number of MRI units, procedures and weighted procedures were provided for the previous full fiscal years being 7/1/2014-6/30/2015, 7/1/2015-6/30/2016, and 7/1/2016-6/30/2017.
- 2. The weighted procedure volumes for the historical periods was based on the actual number of inpatient MRI scans and MRI scans with contrast. The scans were weighted according to the weight factors listed in the 2017 SMFP for MRI scanners.
- 3. There is only one column for Interim Full Fiscal Year, which was identified as 7/1/2019-6/30/2020 as it was the closest interim year to the beginning of the project. For informational purposes, the entire interim period is listed in the chart below:

NHPMC	Interim Year – 7/1/2017- 6/30/2018	Interim Year – 7/1/2018- 6/30/2019	Interim Year – 7/1/2019- 6/30/2020
# of Units	2	2	2
# of Procedures	9876	10301	10744
# of Weighted Procedures	13112	13675	14264

NH Presbyterian concludes this portion of its application on the following page, stating:

6. The utilization for Project Years 1-3 are based on the MRI projections outlined in Section Q and reflect the addition of the proposed MRI scanner.

However, no such MRI projections are included anywhere in NH Presbyterian's application. NH Presbyterian does not demonstrate how it determined its projected utilization. As such, NH Presbyterian fails to demonstrate that its utilization projections are reasonable or supported.

As noted above, NH Presbyterian's related entities own multiple existing and approved fixed MRI scanners in Mecklenburg County. On page 57 of its application in response to the performance standards for MRI scanners at 10A NCAC .2703(b)(3)(E), NH Presbyterian states:

- (3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:
 - (A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,
 - (B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,
 - (C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,
 - (D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or
 - (E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

Novant Health projects its annual average weighted MRI scan volume for each existing, approved, and proposed fixed MRI scanner owned and operated by Novant Health in Mecklenburg County to be 5,006 weighted MRI procedures per fixed MRI scanner in Project Year 3. This exceeds the threshold of 4,805 weighted MRI scans per scanner. See Section Q for the utilization projections and assumptions.

However, Section Q of NH Presbyterian's application does not include any utilization projections or assumptions for any of Novant Health's fixed MRI scanners. As noted above, Novant Health's fixed MRI scanners currently operate at more than 8,000 procedures below target utilization. Yet, NH Presbyterian has provided no utilization projections, methodology, or assumptions to demonstrate the projected utilization for any of Novant Health's fixed MRI scanners. As such, NH Presbyterian fails to demonstrate that its utilization projections for each of Novant Health's existing, approved, or proposed fixed MRI scanners are reasonable or supported.

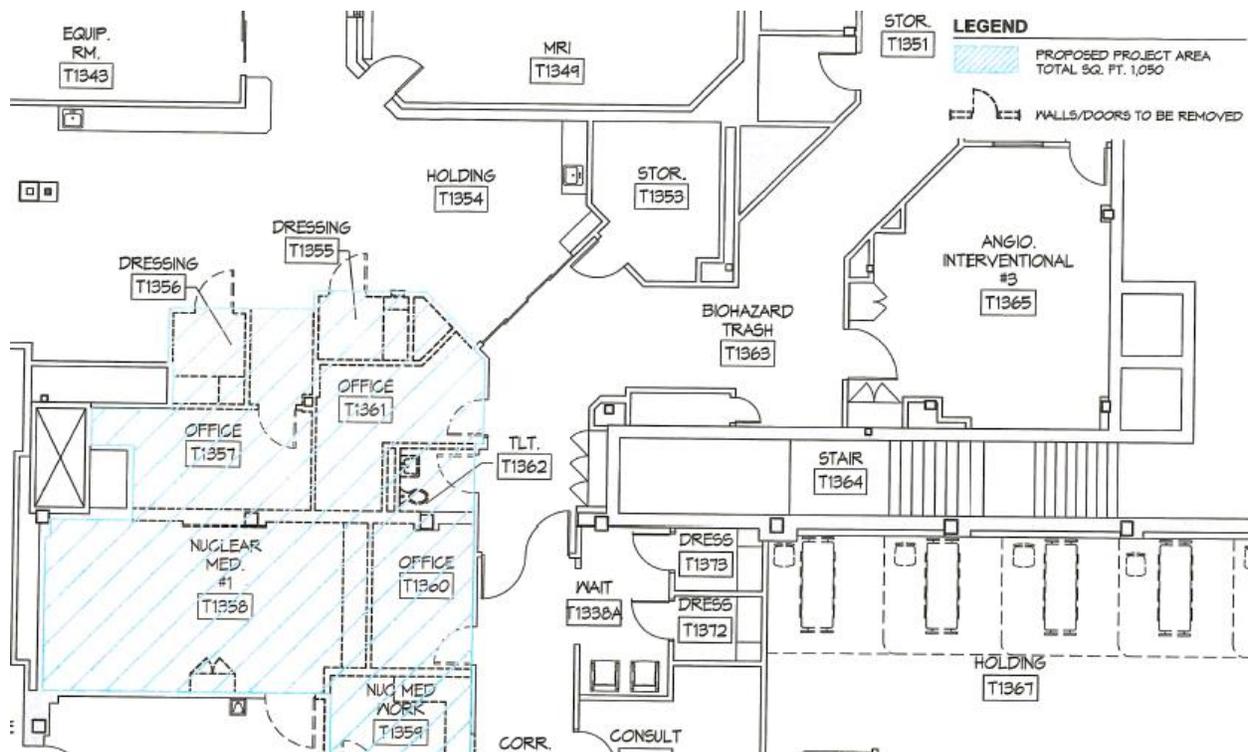
While Novant Health may file additional letters of support during the public period, the Agency has stated that *"all information the applicant intends to rely on to demonstrate conformance of the application with the review criteria must be provided by the applicant in its application when first submitted to the agency"* (see Attachment 1 for a July 10, 2003 letter from CON regarding Letters of Support Submitted for Certificate of Need Applications). Further, pursuant to 10A NCAC 14C .0204, *"[a]n applicant may not amend an application."*

Further, it would be inappropriate for Novant Health, the Agency, or any other person to create a methodology or assumptions for NH Presbyterian's utilization projections. This act would deprive CHS Pineville or any member of the public from commenting on the methodology.

Based on the discussion above, it is clear that NH Presbyterian's projected utilization is unsupported. As such, NH Presbyterian's application is non-conforming with Criteria 1, 3, 4, 5, 6, 18a, and the performance standards in the MRI rules (10A NCAC 14C .2703, particularly .2703(3),(4), and (6)).

Failure to include all capital costs

In the line drawings in Exhibit K-2 of NH Presbyterian's application, the proposed project area is identified as an existing nuclear medicine room as shown in the excerpt below (see Attachment 2 for the existing line drawing in question).



On page 61 of its application, NH Presbyterian states:

The space where one nuclear medicine camera resides today will be renovated for the proposed MRI scanner. NHPMC will transition future nuclear medicine stress tests to be performed as MR stress tests to bring the stress test process up to current standards of care. Thus, no equipment or services are being reduced or eliminated.

NH Presbyterian states that no equipment or services are being reduced or eliminated. But, NH Presbyterian does not identify where the existing nuclear medicine camera will be relocated. NH

Presbyterian states that nuclear medicine stress tests will be transitioned to MRI equipment, but there are additional types of procedures performed on nuclear medicine equipment that are not appropriate for MRI equipment. NH Presbyterian does not address how these non-stress tests will be provided in the future. Moreover, the proposed capital cost of the project does not appear to include the cost of relocation of the nuclear medicine camera. As such, NH Presbyterian appears to have understated the capital cost for its project. If, in fact, NH Presbyterian is eliminating the existing nuclear medicine camera, it has stated the opposite in its application. Specifically, in response to Section D-Criterion 3a, NH Presbyterian states that its project “does not involve reducing the number of beds or equipment on an existing or approved campus” (page 61) and that this Criterion is not applicable, as shown below.

SECTION D - “CRITERION (3a)” - G.S. 131E-183(a)(3a)

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

For change of scope or cost overrun applications, skip to Section D, Question 5.

1. Does the proposal in this application involve?

This proposal does not involve reducing the number of beds or equipment on an existing or approved campus; and does not involve the relocation of beds services to another facility or campus; and does not involve eliminating beds, services or equipment on an existing or approved campus.

- (a) Reducing the number of beds or equipment on an existing or approved campus?
Yes _____ No X
- (b) Relocating beds, services or equipment to another facility or campus?
Yes _____ No X
- (c) Eliminating beds, services or equipment on an existing or approved campus?
Yes _____ No X

...

3. Utilization of the Beds, Services or Equipment that will Continue to be Offered at the Existing or Approved Campus – Complete Form C Utilization, which is found in Section Q.

Not Applicable. MRI services and Nuclear Medicine services will continue to be offered at NHPMC at the existing hospital facility. See Section Q for Form C Utilization for MRI services.

As such, if the existing nuclear camera will be eliminated, NH Presbyterian has failed to demonstrate that the needs of the population presently served will be adequately met as required by Criterion 3a.

Based on this issue, NH Presbyterian failed to demonstrate the availability of funds for capital needs. NH Presbyterian should be found non-conforming with Criterion 5.

Failure to Demonstrate Financial Feasibility

As shown below, NH Presbyterian’s pro forma financial statements include multiple errors and understate expenses throughout the projection period. The following analyses present these issues, in turn.

- Understatement of Staffing Expenses

NH Presbyterian understated its staffing expense for its proposed MRI service in the first project year based on the detailed staffing information presented in Form H. According to NH Presbyterian’s Form H, the 12 FTEs that staff the MRI service during the first project year have a total salary expense of \$976,298. However, the salary expense on Form F.4 for the first project year is incorrectly shown to be \$890,291. Projected Payroll Taxes and Benefits on Form F.4 for the first project year, assumed to be 25 percent of salaries, are also understated based on incorrect salary expense. As a result, NH Presbyterian understated its Total Salary Expense and Payroll Taxes and Benefits by \$107,509 in the first project year, as shown in the table below.

	<i>PY1 per NH Presbyterian</i>	<i>PY1 Revised</i>	<i>Difference</i>
Total Salaries	\$890,291	\$976,298	(\$86,007)
Payroll Taxes and Benefits	\$222,573	\$244,075	(\$21,502)
Total	\$1,112,864	\$1,220,373	(\$107,509)

Please note that NH Presbyterian also failed to accurately reflect its payroll taxes and benefits assumption uniformly. In the six month partial interim year, January 1, 2020 to June 30, 2020, on Form F.4, NH Presbyterian projected \$87,040 in Payroll Taxes and Benefits, which only represent 12.5% of the total projected salaries for the six-month time period. This results in the understatement of operating expenses by \$43,521.

- Failure to Accurately Include Assumed Annual Inflation

NH Presbyterian understated total operating expenses of its proposed MRI service as it failed to appropriately calculate its projected expenses based on its annual inflation assumptions. On Form F.4, NH Presbyterian presents a six month partial interim year, January 1, 2020 to June 30, 2020. As shown below, the annualized value of Medical Supplies, Other Supplies, and Drugs during this partial interim year shown on Form F.4 are identical to the amounts for these expenses in the first project year, which begins six months later. This demonstrates that the NH Presbyterian failed to apply its annual inflation assumption accurately and excluded six months of inflation resulting in understated expenses for project years one, two, and three.

	<i>NH Presbyterian Form F.4 Interim Year (01/01/2020 to 06/30/2020)</i>	<i>NH Presbyterian Interim Year annualized (01/01/2020 to 12/31/2020)</i>	<i>NH Presbyterian Form F.4 PY1 (07/01/2020 to 06/30/2021)</i>
Medical Supplies	\$117,589	\$235,178	\$235,178
Other Supplies	\$2,316	\$4,632	\$4,631
Drugs	\$2,059	\$4,118	\$4,118

In order to accurately state its projected expenses, NH Presbyterian should have applied annual inflation to the second half of the first project year. Based on its Form F.4 assumptions, NH Presbyterian assumes that Medical Supplies, Other Supplies, and Drugs “are based on historical

expenses and inflated 3 percent". The table below demonstrates projected Medical Supplies, Other Supplies, and Drugs for each Calendar Year (CY) based on 3.0 percent annual inflation and calculates the amounts for NH Presbyterian's project year one (July 1, 2020 to June 30, 2021) assuming project year one is equal to 50 percent of CY 2020 plus 50 percent of CY 2021 in order to accurately reflect the impact of the assumed annual inflation.

	CY16	CY17	CY18	CY19	CY20	CY21	CAGR*	PY1
Medical Supplies	\$208,953	\$215,222	\$221,678	\$228,329	\$235,178	\$242,234	3.0%	\$238,706
Other Supplies	\$4,115	\$4,238	\$4,366	\$4,497	\$4,631	\$4,770	3.0%	\$4,701
Drugs	\$3,659	\$3,769	\$3,882	\$3,998	\$4,118	\$4,242	3.0%	\$4,180

*Compound annual growth rate used by NH Presbyterian over the projection period excluding unexplained anomalies.

NH Presbyterian appears have made the same miscalculation in its projected Housekeeping/Laundry, Equipment Maintenance, Depreciation-Equipment, Outside Services, and Other Indirect/Corporate Overhead Expense. The table below demonstrates projected expenses for each category by Calendar Year (CY) based on NH Presbyterian's assumed annual inflation rates for each expense and calculates the amounts for NH Presbyterian's project year one (July 1, 2020 to June 30, 2021) assuming project year one is equal to 50 percent of CY 2020 plus 50 percent of CY 2021 in order to accurately reflect the impact of the assumed annual inflation.

	CY16	CY17	CY18	CY19	CY20	CY21	CAGR*	PY1
Housekeeping/Laundry	\$12,600	\$13,104	\$13,628	\$14,173	\$14,740	\$15,330	4.0%	\$15,035
Equipment Maintenance	\$19,654	\$20,440	\$21,258	\$22,108	\$22,992	\$23,912	4.0%	\$23,452
Depreciation-Equipment	\$412,334	\$416,457	\$420,622	\$424,828	\$429,076	\$433,367	1.0%	\$431,222
Outside Services	\$21,143	\$21,989	\$22,868	\$23,783	\$24,734	\$25,724	4.0%	\$25,229
Other Indirect/Corporate Overhead	\$428,000	\$451,540	\$476,375	\$502,575	\$530,217	\$559,379	5.5%	\$544,798

*Compound annual growth rate used by NH Presbyterian over the projection period excluding unexplained anomalies.

Please note that NH Presbyterian's Form F.4 assumptions state that projected Equipment Maintenance is "based on experience and are inflated 3 percent." However, NH Presbyterian does not appear to account for its proposed additional MRI scanner. As shown in CHS Pineville's pro forma financial statements, it is reasonable to assume that an additional MRI scanner will result in an increase in Equipment Maintenance expense, beyond inflation, in order to maintain an additional unit of equipment (after the warranty period). CHS Pineville does not believe NH Presbyterian's projected expense is sufficient to support the maintenance of its two existing and one proposed MRI scanners. As shown in its financial statements, CHS Pineville projects maintenance expense of \$69,554 for two MRI scanners in PY3. Even after correcting for the assumed inflation rate, NH Presbyterian's Equipment Maintenance expense is \$23,452 in the first project year for three MRI scanners.

- Depreciation

NH Presbyterian’s Form F.4 shows a line item for Depreciation-Buildings that shows zero expense from CY 2016 until project year one. Given that fact, CHS Pineville presumes that this expense is mislabeled and represents the depreciation expense associated with the proposed project, or Project Depreciation. While NH Presbyterian does include another depreciation line item, Depreciation-Equipment, that expense decreases over time does not appear to accurately reflect additional depreciation expense that will result from the proposed project. However, the mislabeled Project Depreciation expense understates the depreciation expense that will result from the project.

On Form F.1a, NH Presbyterian states that the total capital cost for the project is \$3,534,994 including \$1,419,206 for medical equipment. NH Presbyterian does not provide the basis for its assumed depreciation expense in its application. However, Novant Health’s 2016 application for a MRI scanner at NH Huntersville assumed that equipment is depreciated over eight years and buildings are depreciated over 10 years. As shown below, assuming depreciable lives of eight years for equipment and 10 years for buildings, consistent with Novant Health’s prior assumptions, NH Presbyterian has understated its Project Depreciation by \$184,632.

	Cost	Depreciable Years	Annual Depreciation
Medical Equipment	\$1,419,206	8	\$177,401
Other Costs (Building)	\$1,573,480	10	\$157,348
Total	\$3,534,994		\$388,980
Total per NH Presbyterian			\$204,348
Difference			(\$184,632)

- Professional fees

NH Presbyterian states in the Form F.4 assumptions that Professional Fees are based on the historical experience of its MRI department. As the excerpt from Form F.4 below shows, projected professional fees fluctuate from CY 2016 to the end of third project year. There is no basis provided for these changes and they do not follow the approach for of the rest of the pro forma.

	CY16	CY17	CY18	CY19	Partial CY21	PY1	PY2	PY3
Professional Fees	\$50,000	\$50,000	\$50,000	\$50,000	\$37,500	\$50,000	\$50,000	\$75,000

- Summary

As shown above, NH Presbyterian’s pro forma financial statements include numerous errors and understated expenses. The table below provides a summary of the analyses above including a revised total operating expense for NH Presbyterian’s MRI service in the first project year.

Total Understated Operating Expenses Resulted from Errors on Form F.4

	<i>PY1 per NH Presbyterian</i>	<i>PY1 Revised</i>	<i>Difference</i>
Total Salaries	\$890,291	\$976,298	(\$86,007)
Payroll Taxes and Benefits	\$222,573	\$244,075	(\$21,502)
Medical Supplies	\$235,178	\$238,706	(\$3,528)
Other Supplies	\$4,631	\$4,701	(\$70)
Drugs	\$4,118	\$4,180	(\$62)
Housekeeping/Laundry	\$14,598	\$15,035	(\$437)
Equipment Maintenance	\$22,771	\$23,452	(\$681)
Professional Fees	\$50,000	\$50,000	\$0
Rental Expense	\$0	\$0	\$0
Depreciation-Buildings	\$204,348	\$388,980	(\$184,632)
Depreciation -Equipment	\$382,788	\$431,222	(\$48,434)
Outside Services	\$24,734	\$25,229	(\$495)
Other Indirect/Corporate Overhead	\$530,044	\$544,798	(\$14,754)
Total Expenses	\$2,586,076	\$2,946,675	(\$360,599)

As shown, NH Presbyterian has understated its operating expense in the first project year by more than \$360,000. Of note, this analysis does not include an adjustment of equipment maintenance expense that would reflect the potential impact of the additional unit of equipment, nor does it include any adjustment to professional fees expense, which is unsupported as discussed above. Of note, this understatement of expense occurs throughout NH Presbyterian’s projection period. The table above only demonstrates the impact for the first project year.

It should also be noted that even assuming its line item expenses are correct, NH Presbyterian total expenses in the third project year are incorrectly totaled. NH Presbyterian projects on its Form F.4 that total expenses for its MRI service in the third project year (July 1, 2022 to June 30, 2023) will be \$2,374,363. However, based on its specific line item expenses in that year, total expenses are \$2,900,544 as shown in the table below. As such, NH Presbyterian understated its expenses by over \$500,000.

	NH Presbyterian Form F.4 PY 3 Expenses
Total Salaries	\$1,035,755
Payroll Taxes and Benefits	\$258,939
Medical Supplies	\$249,501
Other Supplies	\$4,914
Drugs	\$4,369
Housekeeping/Laundry	\$11,055
Equipment Maintenance	\$17,244
Professional Fees	\$75,000
Rental Expense	\$0
Depreciation-Buildings	\$204,348
Depreciation-Equipment	\$424,828
Outside Services	\$24,734
Other Indirect/Corporate Overhead	\$589,857
Total Expenses	\$2,900,544
Stated Total Expenses	\$2,374,363
Difference	(\$526,181)

Again, even assuming its expenses as listed are correct, NH Presbyterian projected lower housekeeping/laundry and equipment maintenance expenses in interim year 2018 than in interim year 2019, contrary to its assumptions that each expense item was projected to grow three percent annually. Further, NH Presbyterian projected lower housekeeping/laundry and equipment maintenance expenses in its third project year than in its second project year. NH Presbyterian provided no explanation for the decrease in these expenses.

NH Presbyterian MRI Service Form F.4 Expenses

	2018	2019	% Change from 2018 to 2019
Housekeeping/Laundry	\$13,628	\$10,630	-22.0%
Equipment Maintenance	\$21,258	\$16,581	-22.0%

NH Presbyterian MRI Service Form F.4 Expenses

	PY 2	PY3	% Change from PY2 to PY3
Housekeeping/Laundry	\$15,182	\$11,055	-27.2%
Equipment Maintenance	\$23,682	\$17,244	-27.2%

Given the above errors in its financial projections, NH Presbyterian's application fails to demonstrate that the financial feasibility of the project is based on reasonable projections of costs and should be found non-conforming with Criterion 5.

COMPARATIVE COMMENTS

Given that both CHS Pineville and NH Presbyterian propose to meet the need for the additional MRI, only one of the applications can be approved as proposed. In reviewing comparative factors that are applicable to this review, CHS Pineville compared the applications on the following factors:

- History of Project Development/Operating History
- Meeting the Need for Additional MRI Capacity
- Geographic Access
- Demonstration of Need
- Access by Underserved Groups
- Revenues
- Operating Expenses

CHS Pineville believes that the factors presented above and discussed in turn below should be considered by the Analyst in reviewing the competing applications.

History of Project Development/Operating History

In recent competitive reviews pursuant to need determinations, the Agency has considered the applicants' comparative effectiveness with regard to history of project development and operating history.

In the 2016 Brunswick County OR Review, the Agency found that the application submitted by Novant Health was the less effective alternative with regard to history of project developed because Novant Health has failed to develop approved ambulatory surgery centers in New Hanover and Franklin counties and “[n]ot developing the above projects, as approved, has left New Hanover and Franklin County residents without the proposed ambulatory surgery facilities: New Hanover County residents were denied access to the approved ambulatory surgical services, because those ORs were subsequently developed by New Hanover Regional Medical Center as hospital-based ORs; and Franklin County residents have yet to be provided access to the approved ambulatory surgery services, eight years later” (page 59).

In the 2017 Union County OR Review, the Agency found that the application submitted by Novant Health was the less effective alternative with regard to operating history because its facility, Novant Health Monroe Outpatient Surgery, “has been licensed to operate as an ambulatory surgical facility since 2009, but since January 2013 has not served any patients. Thus it has submitted at least three license renewal applications to the Division of Health Service Regulation since it closed in January 2013” (page 42).

As noted above, the inventory of MRI equipment in Mecklenburg County includes the following approved, but not yet operational scanners:

- NH Matthews per Project ID # F-8688-11
- OrthoCarolina Ballantyne per Project ID # F-10287-14
- The conversion of Project ID # F-8327-08 to a fixed MRI at NH Huntersville
- CIS-Huntersville per Project ID # F-11182-16

With regard to the 2016 Mecklenburg County MRI Review, Novant Health is permitted to convert Project ID # F-8327-08 to a fixed MRI at NH Huntersville as a result of a settlement with the Agency related to a contested case involving Project ID # F-11184-16. However, Novant Health is prohibited from developing that project until April 2018. Additionally, CIS (a joint venture of CHS and Charlotte Radiology) is approved to develop a fixed MRI scanner at CIS-Huntersville pursuant to Project ID # F-11182-16. That project is scheduled to be operational in January 2018, based on its most recent progress report, which is six months earlier than the operational date identified in the timetable on its Certificate.

Neither CHS nor CIS have any other approved but not yet developed fixed MRI scanners in Mecklenburg County or anywhere else in the state.

Thus, Novant is a less effective alternative with regard to history of project development/operating history.

Meeting the Need for Additional Fixed MRI Capacity

The 2017 SMFP identifies a need for one additional fixed MRI scanner in Mecklenburg County. As shown above, CHS/CIS fixed MRI scanners have the highest weighted average MRI utilization per fixed magnet among all providers in Mecklenburg County. By contrast, NH Presbyterian and other Novant Health fixed MRI scanners have the lowest weighted average MRI utilization per fixed magnet in the county. Of CHS and CIS's fixed MRI scanners, CHS Pineville's is the most highly utilized. In fact, CHS Pineville's fixed MRI scanner is the most highly utilized fixed MRI scanner in the state (and more highly utilized than NH Presbyterian) and has been so for the last three years. As such, the need identified in the 2017 SMFP is most heavily influenced by the MRI utilization of CHS/CIS and the greatest need within CHS/CIS is at CHS Pineville.

Both projects propose to develop additional fixed MRI capacity in existing space. NH Presbyterian projects that its additional fixed MRI scanner will be operational in July 2020. By comparison, CHS Pineville projects that its additional fixed MRI scanner will be operational in January 2019, or 18 months before the NH Presbyterian project is complete.

Therefore, with regard to meeting the need for additional fixed MRI capacity, CHS Pineville is the more effective alternative.

Geographic Access

Both applications propose to add fixed MRI capacity to an existing facility that offers fixed MRI services. CHS Pineville proposes to develop the additional fixed MRI scanner at its hospital, the location with the greatest need. Therefore, with regard to geographical access, CHS Pineville is comparatively superior to NH Presbyterian.

Demonstration of Need

CHS Pineville adequately demonstrates that the projected utilization of CHS/CIS's existing, approved, and proposed fixed MRI scanners are based on reasonable and supported assumptions. Therefore, CHS Pineville demonstrates the need the population it projects to serve has for the proposed fixed MRI

scanner. NH Presbyterian does not demonstrate that projected utilization of Novant Health’s existing, approved, and proposed fixed MRI scanners is based on reasonable and adequately supported assumptions. Therefore, NH Presbyterian did not demonstrate the need the population it projects to serve has for the proposed fixed MRI scanner. Therefore, the proposal submitted by CHS Pineville is the more effective alternative with regard to demonstration of need.

Access by Underserved Groups

The following table illustrates the percent of total MRI procedures to be provided to Medicaid and Medicare recipients during second project year as stated in Section L.3 of the respective applications:

	<i>CHS Pineville</i>	<i>NH Presbyterian</i>
Percent of Total Procedures to be provided to Medicare Recipients	45.6%	41.0%
Percent of Total Procedures to be provided to Medicaid Recipients	5.6%	11.0%
Total	51.2%	52.0%

As shown above, CHS Pineville projects to serve a higher percentage of Medicare MRI patients compared to NH Presbyterian. NH Presbyterian projects to serve a higher percentage of Medicaid MRI patients.

The following table illustrates each applicant’s total number of MRI procedures projected to be provided by the proposed additional scanner to Medicare and Medicaid recipients in the third project year.

	<i>CHS-Pineville PY3</i>	<i>NHPMC PY3</i>
Total Medicare Procedures	4,156	4,998
Total Medicaid Procedures	514	1,341
# of MRI Scanners	2	3
# of Medicare MRI Procedures Provided by Additional Unit	2,078	1,666
# of Medicaid MRI Procedures Provided by Additional Unit	257	447
Total # of Medicare/Medicaid MRI Procedures Provided by Additional Unit	2,335	2,113

In total, the two applicants project a comparable percentage of combined Medicare/Medicaid MRI patients. CHS Pineville projects to serve a greater number of Medicare patients with the proposed additional scanner and a greater number of combined Medicare and Medicaid patients than NH Presbyterian. Therefore, with respect to access by underserved groups, CHS Pineville is the more effective alternative.

Revenues

NH Presbyterian's proposed project years are based on state fiscal years while CHS Pineville's project years are based on calendar years. As noted above, the proposed project at CHS Pineville is assumed to begin operation on January 1, 2019. NH Presbyterian's first date of operation is over 18 months later, on July 1, 2020. To reasonably compare projected revenues for the respective applications, CHS Pineville compared the projected revenues for NH Presbyterian's first project year, which begins July 1, 2020, with CHS Pineville's second project year, which begins January 1, 2020. The following table illustrates each applicant's projected total gross revenue per procedure in these years.

	<i>CHS Pineville (PY2)</i>	<i>NH Presbyterian (PY1)</i>
Gross Revenue	\$31,384,208	\$39,962,084
Unweighted MRI Procedures	8,995	10,741
Gross Revenue per Procedure	\$3,489	\$3,721

As shown above, CHS-Pineville projects lower average gross revenue per MRI procedure. Therefore, CHS Pineville is the more effective alternative with regard to gross revenue.

The following table illustrates each applicant's projected total net revenue per procedure in these years.

	<i>CHS Pineville (PY2)</i>	<i>NH Presbyterian (PY1)</i>
Net Revenue	\$5,909,945	\$12,919,050
Unweighted MRI Procedures	8,995	10,741
Net Revenue per Procedure	\$657	\$1,203

As shown above, CHS Pineville projects lower average net revenue per MRI procedure. Therefore, CHS Pineville is the more effective alternative with regard to net revenue.

Operating Expenses

Using the same project years for each application as noted above, CHS Pineville compared operating expenses. As demonstrated in the discussion above on the failure to demonstrate financial feasibility, NH Presbyterian understated its operating expenses throughout the projection period. As such, CHS Pineville used the revised project year one operating expenses for NH Presbyterian in the table below, which are still understated as they do not include any adjustments for equipment maintenance and professional fees.

	<i>CHS Pineville (PY2)</i>	<i>NH Presbyterian (PY1)</i>
Operating Expenses	\$2,335,515	\$2,946,675
Unweighted MRI Procedures	8,995	10,741
Operating Expenses per Procedure	\$260	\$274

As shown above, CHS Pineville projects lower average operating cost per MRI procedure. Therefore, CHS Pineville is the more effective alternative with regard to operating expenses.

SUMMARY

As noted previously, CHS Pineville maintains that NH Presbyterian's application cannot be approved as proposed given its non-conformity with Criteria 1, 3, 4, 5, 6, 18a, and 10A NCAC 14C .2703. As such, CHS Pineville is the only approvable application. Based on the comparative analysis, CHS Pineville believes that its application represents the most effective alternative for meeting the need in the 2017 SMFP for an additional fixed MRI scanner in Mecklenburg County. As such, the Agency can and should approve CHS Pineville.

Attachment 1

NC Division of Health Service Regulation

Certificate of Need Section

Letters of Support Submitted for Certificate of Need Applications

To: Interested Parties

From: Lee B. Hoffman, Chief, CON Section

Date: July 10, 2003

The purpose of this memorandum is to clarify procedures relative to acceptance of letters of support for a project after the application has been filed to assure conformance with the Certificate of Need law and administrative rules regarding the written comment period and amendments to the application.

From this date forward, any letters of support or petitions for a project must be received by the CON Section no later than the last day of the written comment period for the application. Any letters or petitions received after that date, including letters and petitions brought to the public hearing, will not be considered by the agency in the review of the project. This procedure is consistent with G.S. 131E-185(1) which states, "Any person may file written comments and exhibits concerning a proposal under review with the department, not later than 30 days after the date on which the application begins review." Additionally, G.S. 131E-185(2) states that at the public hearing "oral arguments may be made regarding the application or applications under review..." Therefore, the law provides for the public to make oral comments at the public hearing. There is no provision in the law allowing the submittal of written comments at the hearing given that it is held more than 30 days after the review begins. However, a speaker may provide the agency a transcript of his/her oral remarks made at the hearing in accordance with G.S. 131E-185(2) which states "any person may submit a written synopsis or verbatim statement that contains the oral presentation made at the hearing." In addition, an applicant may submit a written response or rebuttal to the written comments made on its application, to the Certificate of Need Section at the public hearing.

As has always been the case, please note that nothing contained in oral or written comments can be used to amend (i.e. revise, change or supplement) the application filed with the Certificate of Need Section. Specifically, [10A NCAC 14C .0204](#)  states, "An applicant may not amend an application. Responding to a request for additional information made by the agency after the review has commenced is not an amendment." Therefore, the application cannot be amended with information contained in any letters or materials received during the written comment period or at the public hearing, even if the applicant states in the application that such letters will be submitted. Consequently, all information the applicant intends to rely on to demonstrate conformance of the application with the review criteria must be provided by the applicant in its application when first submitted to the agency.

If you have any questions regarding this matter, please submit them in writing to Lee Hoffman, Certificate of Need Section, to assist the agency in making consistent responses to all inquiries.

 Denotes link to site outside of N.C. DHSR.

This page was last modified on May 27, 2008.

[Division of Health Service Regulation](#)

Attachment 2

