ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: February 12, 2014

PROJECT ANALYST: Gene DePorter
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: A-10222-13/WestCare, Inc. d/b/a MedWest-Harris /Develop one C-Section room and renovate Women's and Children's inpatient services /Jackson

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, ambulatory surgical operating rooms, or home health offices that may be approved.

NA

WestCare, Inc. d/b/a MedWest-Harris Hospital (MW-H) in Sylva is an 86 bed non-profit hospital with six shared inpatient/ambulatory surgery operating rooms (one of which serves as a C-Section room). The applicant proposes to develop one dedicated C-Section room in new construction located on the third floor of its facility adjacent to Women's and Children's inpatient services which will be renovated in conjunction with the C-Section suite development. Carolinas HealthCare System (CHS) has a Management Services Agreement for overseeing the day-to-day operations of MW-H.

The applicant does not propose to add any new operating rooms, health service facility beds, medical equipment or new services for which there is a need determination in the 2013 State Medical Facilities Plan (2013 SMFP) nor is the applicant proposing the reduction or elimination of beds, operating rooms, medical equipment or other existing services. Further, the 2013 SMFP, page 71 states that: "*Dedicated C-Section Operating Rooms" and associated cases are excluded from the calculation of need for additional "operating rooms" by the standard methodology; therefore, hospitals proposing to add a new operating room for use as a "Dedicated C-Section Operating Room" shall apply for a certificate of need, without regard to the need determinations in Chapter 6 of this Plan.*" There are no policies in

the 2013 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

WestCare, Inc. d/b/a MedWest-Harris (MW-H) proposes to develop one dedicated C-Section operating room at 68 Hospital Drive, in Sylva. The hospital has 6 shared operating rooms (one of which services as a C-Section room) and 1 endoscopy procedure room located on the first floor in the hospital's existing surgical suite. The applicant is proposing to develop one dedicated C-Section operating room and related support areas in 900 square feet of new construction on the third floor of the hospital. Further, MW-H proposes that 15,705 square feet of existing space on the third floor will be renovated for Women's and Children's inpatient services.

Population to Be Served

In Section III.1, pages 72-75, the applicant states that Jackson County is the primary service area for MW-H; while Swain, Graham, Macon and Haywood counties constitute the secondary service area. The following table provides the demographics for the total population of the primary and secondary service area from FY 2013 to FY 2018, and resulting Compound Annual Growth Rate (CAGR) per county.

MW-H
Current and Projected Population
Compound Annual Growth Rates
For Fiscal Years 2013 and 2018

	Current Population		Projected Population		CAGR
	FFY 2013		FFY 2018		FFY 2013 to 2018
County	Population	% of Population	Population	% of Population	
Jackson	41,111	26.0%	42,725	26.1%	0.8%
Swain	14,652	9.0%	15,444	9.4%	1.1%
Macon	34,164	22.0%	34,803	21.2%	0.4%
Graham	8,994	6.0%	9,384	6.0%	0.9%
Haywood	59,765	38.0%	61,564	38.0%	0.6%
Total SA	158,686	100.0%	163,920	100.0%	0.7%

*Source: Section III.1, page 57

In Section III. 1(a), page 53, the applicant provides the population of women of child bearing age (18-44) the service area has. It is projected to remain relatively constant, as shown in the following table:

MedWest-Harris Service Area
Child Bearing Population Female 18-44

Year	Females 18-44 2012 to 2018	% Change
2012	**24,914**	-
2013	**25,059**	**0.6%**
2014	**25,122**	**0.3%**
2015	**25,148**	**0.1%**
2016	**25,189**	**0.2%**
2017	**25,314**	**0.5%**
2018	**25,547**	**0.9%**

Source: Exhibit 9, NC OSBM, pages 223-224

In Section III, page 70, the applicant states that approximately 45% of the hospital's total acute care patients are from Jackson County. In total the primary and secondary service area represents about 92% of all acute care patients at MW-H. The following tables provide the historic and projected patient origin for Post-Partum patients and patient origin for births for projected fiscal years 2016 and 2017, pages 57-58, and 74.

MW-H-Historic and Projected Post-Partum Patient Origin
For Fiscal Years 2012, 2016 and 2017

	Historical		Projected			
	FFY 2012		FFY 2016		FFY 2017	
County	# of patients	% of patients	# of patients	% of patients	# of patients	% of patients
Jackson	249	39.6%	259	39.6%	262	39.6%
Swain	139	22.1%	145	22.1%	148	22.3%
Macon	124	19.8%	129	19.8%	130	19.7%
Graham	54	8.6%	56	8.6%	57	8.6%
Haywood	30	4.7%	31	4.7%	31	4.7%
Other**	33	5.2%	34	5.2%	35	5.2%
Total	**628**	**100.0%**	**655**	**100.0%**	**662**	**100.0%**

*Source: Section III.5 (C), page 74; 71 and 65.
**"Other" includes Buncombe, Cherokee, Clay, Guilford, Henderson, Mecklenburg and Transylvania counties and counties in North Carolina and other states.

The data in the above and following tables indicates the following for both post-partum and newborns:

- Jackson County accounted for 40% MW-H Post-Partum and new born patients with Swain and Macon Counties accounting for 20% each or approximately 80% of all post-partum new born patients in FY 2012 and 82% in FY 2016 and 2017.

- The remaining counties in the service area, Graham and Haywood, combined are the source of approximately 13% MW-H post-partum and new born patients, current and projected.

MW-H-Historic and Projected Patient Origin for Births
(Includes Vaginal Deliveries and C-Sections)
For Fiscal Years 2012, 2016 and 2017

	Historical		Projected			
	FFY 2012		FFY 2016		FFY 2017	
County	**# of patients**	**% of patients**	**# of patients**	**% of patients**	**# of patients**	**% of patients**
Jackson	250	41.1%	261	41.1%	263	41.1%
Swain	125	20.5%	134	21.1%	136	21.3%
Macon	122	20.0%	124	19.5%	125	19.4%
Graham	51	8.3%	53	8.3%	53	8.3%
Haywood	27	4.5%	27	4.3%	27	4.2%
Other**	35	5.7%	36	5.7%	36	5.7%
Total	**609**	**100.0%**	**634**	**100.0%**	**641**	**100.0%**

*Source: Section III.5 (C), page 74, 71 and 65.
** "Other" includes Buncombe, Cherokee, Clay, Guilford, Henderson, Mecklenburg and Transylvania counties.

The applicant adequately identified the population to be served by this project.

Need for a Dedicated C-Section Operating Room

On page 50, the applicant discusses the following current patient experience:
Currently, laboring mothers who come to MW-H are taken to labor and delivery rooms on the west wing of the third floor. If a C-Section is needed, patients are transported from the labor and delivery room, down a public hallway to elevators. At this point they wait for an elevator to take them down two floors to the operating room suite to be prepped for their C-Section. In Section III. 1(a), page 50 the applicant states, "*This travel time is unnecessary, inefficient, poses a potential safety concern, and is not an ideal experience for laboring mothers.*"

In Section III.1 (a), pages 49-50, the applicant states:

> *"MedWest-Harris has been providing obstetrical services, including C-Sections since it began operations in 1929. As the only hospital in Jackson County, MedWest-Harris has historically performed a majority of the deliveries west of Asheville in Western North Carolina. Currently, MedWest-Harris does not have a dedicated C-Section operating room, although this has become the standard in hospitals across the country. MedWest-Harris believes that by developing a dedicated C-Section room is space located adjacent to existing women's and children's services, the hospital can provide more effective and safe care for its patients and other obstetrical services consistent with today's expectations. …From a physician and staff perspective, the current lack of a*

dedicated C-Section operating room at MedWest-Harris is not only unsafe and inefficient from a patient standpoint but also from a scheduling and efficiency standpoint. One of the hospital's six shared operating rooms, specifically OR 6, is held at all times of the day for C-Section procedures. This has had a major impact on other surgical specialties at MedWest-Harris, specifically ENT, orthopedics, ophthalmology, and general surgery."

The applicant states in pages 51-52, that developing a dedicated C-Section suite on the third floor will open operating time in the 6 room operating suite for ENT, orthopedics, general surgery (new surgeon started September 27, 2013), and ophthalmologists (actively being recruited). The women's and children's services will be bringing in a new OB/GYN physician in the summer of 2014.

The applicant also notes the following on page 52:

"The addition of a dedicated C-Section room will effectively co-locate all inpatient women's and children's services on the third floor, improving staff efficiency and providing patients a better, safer experience."

In Section III.1(a), page 54, the applicant states:

"In order to create a positive healthcare environment for the residents of Jackson and surrounding counties and the prospective patients of MedWest-Harris it is imperative that MedWest-Harris be perceived as a hospital that is able to provide virtually all the needs of their family in the present and coming years. The current perception of patients does not support this notion, as many of the patient and post-partum rooms have not been touched since the 1980's. With a new façade on its women's and children's services rooms, MedWest-Harris will be able to better provide for their patients' wants and needs.

One of the many concerns voiced by MedWest-Harris' physicians is that because many of their patients recognize that the hospital facility is outdated, the patients then also perceive that the care provided must be out-of-date as well. Patients have voiced dissatisfaction to their physicians about the poor aesthetics in patient rooms and in waiting areas throughout the hospital, but particularly relative to women's and children's services. In turn the outdated appearance of the hospital and resulting patient complaints makes it difficult to recruit needed physicians to the community. MedWest-Harris expects that the proposed project will eliminate these concerns and will provide a more aesthetically pleasing environment in which patients will give birth to their children and return for other healthcare needs.

The proposed renovations and upgrades to patient rooms, and the third floor in general, will also add more safety and security measures to protect patients. These new security measures will be in line with those of the National Centers for Missing and Exploited Children. Whereas laboring mothers currently have to go through public access halls frequently when seeking treatment, the proposed project will consolidate

all obstetrics on one floor and include the installation of several controlled access entryways in all major hallways of the third floor. This will give patients a more private and family centered experience while also creating a safer atmosphere for both patients and staff."

As stated on page 49, the basis of this application is both qualitative and quantitative. The qualitative issues addressed include issues of safety, security, efficiency and an improved environment for patients, families, physicians and staff.

Methodology by Service Component

The methodology for each service component is as follows:

As discussed above and on page 57 of the application, the 2013 to 2018 service area population compound annual growth rate (CAGR) indicates stable to limited growth, as shown in the following table,

Time Frame	Jackson	Swain	Macon	Graham	Haywood	Total SA
2013	41,111	14,652	34,164	8,994	59,765	158,686
2018	42,725	15,444	34,803	9,384	61,564	163,920
Pop. CAGR*	0.8%	1.1%	0.4%	0.9%	0.6%	0.7%

* Source: NC OSBM, see Exhibit 9.

The following table demonstrates the FFY 2012 obstetric delivery discharges in the five county service area,

FFY 2012	Jackson	Swain	Macon	Graham	Haywood	Total SA	% Market Share
MW-H	249	135	127	54	31	**596**	**39.6%**
Other Providers	76	97	207	26	504	910	60.4%
Total Market Discharges	325	232	334	80	535	1506	100.0%

Data in the above table indicates MW-H had a 39.6% market share for obstetrics discharges in 2012 for its five county service area. The applicant expects only future growth in obstetric delivery discharges over the next five years will be limited to the population CAGR for 2013-2018 shown above.

In Section III.1(b), pages 57 to 60, the applicant provides its methodology for growing service area obstetric discharges from 2013 to 2018. The following table shows the MW-H existing obstetric discharges held constant from 2013 to 2018 with the incremental growth added in from 2016 to 2018 for both MW-H OB discharges and for in-migration discharges.

Fiscal Year	MW-H OB Discharges	In-migration Discharges	MW-H Total OB Discharges	ALOS	Total Days
2013	596	33	629	2.1	1,298
2014	596	33	629	2.1	1,298
2015	596	33	629	2.1	1,298
2016 (PY 1)	621	34	655	2.1	1,352
2017 (PY 2)	627	35	662	2.1	1,366
2018 (PY 3)	633	35	668	2.1	1,379

In-migration, from beyond the secondary service area, is projected to remain at 5.2% and average length of stay (ALOS) is projected to remain at 2.1 days. The projected market share for MW-H obstetrical discharges between 2016 and 2018 is 40.4%, as shown on page 60.

The applicant believes that the proposed project will improve the state of women's services at MW-H and result in 1,379 post-partum patient days in PY 3, FFY 2018.

Using the historical ratio of births to post-partum discharges, MW-H projects 0.97 births for every post-partum discharge. It projects the ratio of vaginal births and C-Sections to remain at their 2012 ratios of 0.76 and 0.21, respectively. The following table provides data from pages 62-63, for total Post-Partum discharges for Vaginal Births and C-Sections for FFYs 2013 through 2018.

Fiscal Year	Post-Partum Discharges	Vaginal Births	C-Sections	Total Births
2013	629	475	134	609
2014	629	475	134	609
2015	629	475	134	609
2016 (PY 1)	655	495	140	634
2017 (PY 2)	662	500	141	641
2018 (PY 2)	668	505	142	647

MW-H states in page 63, that it currently has three obstetricians and three midwives on staff. One obstetrician is nearing retirement. The hospital's recruitment efforts have a new obstetrician due December 2014.

MW-H proposes to renovate existing storage space to create a new nursery. The new nursery will be located adjacent to the C-Section Suite on the West side of the third floor. MW-H has 11 bassinets which allows for one per each Post-Partum room and three left for twins or babies remaining after mothers have gone home.

The dedicated C-Section room will be built on existing roof space and nursery space on the third floor. This allows for co-location with existing women's and children's services and

more efficient use of space and resources while freeing an existing OR for scheduling by surgical specialties.

Currently Triage patients are seen in the labor and delivery rooms. In the future these patients will be seen in the support space adjacent to the C-Section suite.

The surgical volume for 5 of the 6 operating rooms is provided in the following table. The projections indicate that the number of inpatient surgical cases will continue to shift from the inpatient to outpatient treatment environment of MW-H. Concurrently, the overall patient volume of the five-county MW-H service area is projected to grow as a function of the five year population CAGR of 0.7% for 2013 to 2018.

Historic and Projected Surgical Services
FY2012 through FY2018

	FFY 2012	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017	FFY 2018
Inpatient Cases	915	786	792	797	802	808	813
% Inpatient Cases	19.1%	16.4%	16.8%	16.8%	14.4%	14.4%	14.4%
Outpatient Cases	3,882	3,908	3,934	3,961	4,785	4,817	4,849
% Outpatient Cases	81.0%	83.3%	83.2%	83.3%	85.6%	85.7%	85.6%
Total Cases	4,797	4,694	4,726	4,757	5,587	5,624	5,662

Source: FFY 12 includes 134 C-Section cases, FFYs 16-18 do not include projected C-Section cases, pages 28 & 33.

In Section III.4 (a), pages 70-74, of the application, the applicant provides the following tables showing the current (2012) and projected (2016-2018) patient origin for the proposed dedicated C-Section operating room, post-partum patient area, newborn nursery, and births in the first two years of operation following completion of the project.

The primary service area is the source of 39% of post-partum patients with the secondary service area representing 55% of the hospital's post-partum patient volume.

Projected Post-Partum Patient Origin: FY2016 - FY2017

County	Year 1 FFY 2016 Projected Discharges	Year 1 % of Total Discharges	Year 2 FFY 2017 Projected Discharges	Year 2 % of Total Discharges
Jackson	259	39.6%	262	39.6%
Swain	145	22.1%	148	22.3%
Macon	129	19.8%	130	19.7%
Graham	56	8.6%	57	8.6%
Haywood	31	4.7%	31	4.7%
Other*	34	5.2%	35	5.2%
Total	655	100.0%	662	100.0%

*Other includes Buncombe, Cherokee, Clay, Henderson, Mecklenburg, Surry, Transylvania, Wayne and Yancey Counties in North Carolina, as well as other states.

Patient Origin of Projected Births (Includes Vaginal Deliveries and C-Sections)
FFY2016 - FFY2017

County	Year 1 FFY 2016 Projected Discharges	Year 1 % of Total Discharges	Year 2 FFY 2017 Projected Discharges	Year 2 % of Total Discharges
Jackson	261	41.1%	263	41.1%
Swain	134	21.1%	136	21.3%
Macon	124	19.5%	125	19.4%
Graham	53	8.3%	53	8.3%
Haywood	27	4.3%	27	4.2%
Other	36	5.7%	36	5.7%
Total	634	100.0%	641	100.0%

*Other includes Buncombe, Cherokee, Clay, Henderson, Mecklenburg, Surry, Transylvania, Wayne and Yancey Counties in North Carolina, as well as other states.

Summary: Women's Services Projected Utilization Data
FY2013 - FY2018

Women's Services	FFY Ending 9/30/13*	FFY Ending 9/30/14	FFY Ending 9/30/15	FFY Ending 9/30/16	FFY Ending 9/30/17	FFY Ending 9/30/18
Post-Partum						
# of Beds	8	8	8	8	8	8
Discharges	629	629	629	655	662	668
Patient Days	1,298	1,298	1,298	1,352	1,366	1,379
Labor, Delivery and C-Section						
# of Births	609	609	609	634	641	647
C-Section Rms.	1	1	1	1	1	1
C-Sections	134	134	134	140	141	142
% C-Sections	22%	22%	22%	22%	22%	22%

Source: Application A-10222-13, page 63.
* FFY Ending 9/30/2013 is based upon FFY data for 2012.

In Section III.5, page 26, the applicant states the patient origin for the dedicated C-Section operating room is based on historical utilization. The applicant also indicates that while MedWest-Harris is not proposing to add any services that it does not already offer, it believes the proposed project will promote more effective delivery of the care it currently provides. The applicant adequately identified the population it proposes to serve.

Project Components

Dedicated C-Section Operating Room

MedWest-Harris does not currently operate a dedicated C-Section room. The hospital currently utilizes one of 6 shared Ambulatory/Inpatient operating rooms located on the first floor for C-Section needs. All other surgical procedures are conducted in the five remaining operating rooms. This project will result in the co-location of a dedicated C-

Section suite in new space on the third floor and existing space to be vacated by the newborn nursery thus improving efficiency in patient care through better spatial relationship of related functions. The dedicated C-Section suite will operate 24 hours per day, seven days per week, 52 weeks per year.

Newborn Nursery

The newborn nursery will be relocated to existing space adjacent to the proposed C-Section suite which currently houses two Post-Partum beds and storage area. (See Exhibit 2 for proposed line drawings)

Post-Partum

The 8 post-partum rooms, displaced by the newborn nursery, will be relocated to spaces that are currently used as a classroom/conference space and lactation room (See Exhibit 2 for proposed line drawings). The project will also upgrade finishes for the remaining post-partum rooms and hallway on the third floor. MedWest-Harris analyzed internal and Truven market data to determine the number of post partum patients that it would serve. The methodology assumes that every existing provider serving MedWest-Harris' five county service area will maintain their existing patient base; that is, projected utilization does not depend on shifting volume from other providers and projected growth in patient discharges is based solely on population growth by county.

Other Project Components

The applicant maintains that the proposed renovations and expansion of the women's and children's unit will add to its effectiveness in serving patients in its service area. The displaced classroom/conference room will be combined with space that currently houses locker room and tub room. In addition, the pediatric bed unit will be renovated. All entrances on the third floor will be converted into controlled access entrances (See Exhibit 2 for proposed line drawings).

In Section III.1 (b), pages 55-65 of the application, the applicant describes its methodology and assumptions as follows:

> *"The project proposes to expand and renovate MedWest-Harris' third floor, which primarily houses its women's and children's services. The proposed expansion and renovation will alleviate deficiencies related to the age of the existing facility and allow for a more appropriate and efficient use of space in which to deliver care."*

In summary, the applicant adequately demonstrates the need the population projected to be served has for the proposed project. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently

served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

In Section III.3, pages 68-70 of the application, the applicant discusses two alternatives it considered prior to selecting the best option.

Maintain Status Quo

MW-H dismissed this option because it would not reduce concerns for safety of mothers and babies such as the travel distance within the hospital from the third floor to the current C-Section location in the main operating suite on the first floor. The applicant states; "*This travel time is unnecessary, inefficient, poses a potential safety concern and is not an ideal experience for laboring mothers.*"

Alternative Renovation Plan

The applicant states that the current C-Section suite is located in 1956 construction which would not provide sufficient clear space and room heights. The existing labor and delivery suite is too small to house the proposed C-Section suite and would result in increased construction cost. Finally the current space could not be reconfigured to provide improved access to the elevator and operating room suite (Reference the line drawings in Exhibit 2). Therefore, MW-H rejected this alternative.

Develop This Project as Proposed

MW-H states that it recognized the opportunity to improve the efficiency, safety and appearance of its women's and children's services by extensively renovating the existing services located on the third floor of the facility. In addition, the construction of 900 square feet of additional space and renovation of 15,705 square feet of existing space will provide sufficient area to accommodate all the components of the Women's and Children's service in a logical, spatial relationship that improves workflow for professional and support staff, increased patient and staff safety, clinical quality, patient privacy, and staff and patient satisfaction. This is the applicant's alternative of choice.

Therefore, the applicant has adequately demonstrated that developing a dedicated C-Section space on the third floor and thereby co-locating this capability with the existing

Women's and Children's services also on the third floor is the applicant's least costly or most cost effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **WestCare, Inc. d/b/a MedWest-Harris shall materially comply with all representations made in the certificate of need application.**

2. **WestCare, Inc. d/b/a MedWest-Harris shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

3. **WestCare, Inc. d/b/a MedWest-Harris shall be licensed for no more than one dedicated C-Section operating room upon completion of this project.**

4. **WestCare, Inc. d/b/a MedWest-Harris shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, pages 106-107, MW-H projects a total capital cost for this project of $4,075,460, including $3,026,000 for construction, $526,530 for fixed and moveable equipment, $475,000 for architect and engineering, $44,000 for other reimbursable costs and $3,930 for furnishings. In Section VIII.3, page 107, and Exhibit 17 of the application, the applicant indicates that the total cost of the proposed project will be funded by a public campaign and the hospital will make up any short fall from hospital reserves.

Exhibit 19 contains a letter dated October 15, 2013 from the Chief Financial Officer of MedWest-Harris, which states the following:

"As the Chief Financial Officer for MedWest-Harris I am responsible for the financial operations of the hospital. As such, I am very familiar with the organization's financial position.

The WestCare Foundation, whose assets are part of WestCare, Inc., will fund the capital costs of the project, estimated to be $4,705,460 with foundation funds. To date $627,938 have been raised by the WestCare Foundation specifically assigned to this project ($390,000 of the raised funds have already been appropriated to A&E

fees). As shown on page 2 of the FY 2012 audited financials included with the application, MedWest-Harris has sufficient cash and short term investments to provide the required capital costs of the proposed project if the WestCare Foundation cannot raise the remaining funds needed."

In Section VIII.8, pages 109-110, the applicant states the following:

"As documented in the funding letters provided in Exhibit 19, the proposed project will be funded through donations to the WestCare Foundation, whose assets are part of WestCare, Inc. A total of $627,938 specifically assigned to this project has been raised by the WestCare Foundation to date ($390,000 of the raised funds have already been appropriated to the A&E fee). As such, the Foundation has $237,938 immediately available for the proposed project. Going forward, the Foundation will continue to raise remaining funds for the proposed project. As the pillar of healthcare service provision for Jackson and the surrounding area, WestCare has a strong presence in its community and a positive reputation. This has contributed to the WestCare Foundation's ability to successfully raise money in the community for various capital projects over the years. Over the years the foundation has raised funds for the provision of mammograms to underserved women in Jackson and Swain Counties, the Harris Regional Hospital ED expansion, the cardiopulmonary rehab department, and the chaplaincy program. Please see Exhibit 19 for documentation of the WestCare Foundation's successful track record with raising philanthropy dollars for capital projects.

…As such MedWest-Harris feels confident in its ability to raise the estimated capital costs for the proposed project. However, please see Exhibit 19 for a letter from Mike McKnight, Chief Financial Office of MedWest-Harris, documenting the commitment to use foundation funds as well as the availability of reserves if the WestCare Foundation cannot raise the remaining funds needed."

In Exhibit 20, the applicant provides a copy of the audited consolidated financial statements for WestCare, Inc. and Affiliates, for the years ended September 30, 2012, and September 30, 2011. The 2012 statement demonstrates that WestCare, Inc. has $3,079,851 in Cash and Cash Equivalents and Short-Term Investments of $11,791,759. Total net assets, (Total Assets–Total Liabilities) equals $9,913,706. On page 112 the applicant states it does not project any start-up or initial operating expenses. Total net assets, (Total Assets – total liabilities) equal $9,913,706. The applicant adequately demonstrated the availability of funds for the capital needs of the project.

The costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements of the application (Financials Tab). The applicant projects revenue will exceed expenses for the first three years of the proposed project, as shown in the following table from page 126.

MedWest-Harris Regional Hospital Summary of Revenue and Expenses (in 000s)	Project Year 1 FFY 2016	Project Year 2 FFY 2017	Project Year 3 FFY 2018
Gross Patient Revenue	$277,300,000	$291,165,000	$305,723,000
Deductions from Gross Patient Revenue	$181,023,000	$190,074,000	$199,578,000
Net Revenue	$ 102,122,000	$107,229,000	$112,590,000
Total Expenses	$ 99,654,000	$102,757,000	$105,989,000
Net Income	$ 2,969,000	$ 4,972,000	$ 7,101,000

From the Pro Forma Section, pages 127-133, the following tables reflect the revenues and expenses of the three primary cost centers involved in the proposed project. Both the Post-Partum beds cost center and the Nursery cost center show losses for the first three years. However, the C-Section cost center, when combined with other surgeries shows a positive cash flow in each of the first three project years.

MW-H Regional Hospital Post-Partum Summary of Revenue and Expenses (in 000s)	Project Year 1 FFY 2016	Project Year 2 FFY 2017	Project Year 3 FFY 2018
Projected # of Discharges	655	662	668
Projected Average Charge per Discharge	$3,963	$4,082	$4,204
Gross Patient Revenue	$2,595,871	$2,700,933	$2,810,201
Deductions from Gross Patient Revenue	$1,731,221	$1,801,287	$1,874,160
Total Revenue	$ 869,715	$ 904,862	$ 941,414
Total Expenses	$1,145,593	$1,176,505	$1,208,327
Net Income	$ -275,878	$ -271,643	$ -266,912

MW-H Hospital Nursery Summary of Revenue and Expenses (in 000s)	Project Year 1 FFY 2016	Project Year 2 FFY 2017	Project Year 3 FFY 2018
Projected # of Births	634	641	647
Projected Average Charge per Treatment	$361	$371	$383
Gross Patient Revenue	$228,685	$237,941	$247,567
Deductions from Gross Patient Revenue	$152,513	$158,686	$165,106
Net Patient Revenue	$ 76,172	$ 79,255	$ 82,461
Total Expenses	$123,933	$127,688	$131,570
Net Income	-$ 47,761	-$ 48,434	-$ 49,109

MW-H Hospital Total Surgical Cases Including C-Section Summary of Revenue and Expenses (in 000s)	Project Year 1 FFY 2016	Project Year 2 FFY 2017	Project Year 3 FFY 2018
Projected # of C-Section Cases	140	141	142
Projected # of Other Surgical Cases	4,789	4,821	4,854
Projected # of Surgical Cases	4,929	4,962	4,996
Projected Average Charge per Surgery	$4,217	$4,343	$4,473
Gross Patient Revenue	$20,783,003	$21,552,089	$22,349,633
Deductions from Gross Patient Revenue	$12,827,372	$13,302,056	$13,794,304
Total Revenue	$ 7,955,631	$ 8,250,033	$ 8,555,329
Total Expenses	$ 6,602,171	$ 6,887,112	$ 7,186,537
Net Income	$ 1,353,460	$ 1,362,921	$ 1,368,792

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. The Financials Tab, pages 136-146 contains all assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates that the immediate and long term financial feasibility of the proposal is based upon reasonable projections of costs and charges for providing dedicated C-Section services co-located on the third floor with Women's and Children services. Therefore, the application is conforming to this criterion.

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

C

MW-H Hospital proposes to develop one dedicated C-section operating room and related support space on the third floor of the hospital. The applicant adequately demonstrates the need for the dedicated C-section operating room. MW-H is the only hospital in Jackson County and has historically performed the majority of the deliveries west of Ashville in Western North Carolina. MW-H states on page 58 that it is the top provider of obstetric delivery services in Jackson, Swain and Graham counties and that those counties do not have an acute care provider that offers inpatient obstetrics. Consequently; the applicant adequately demonstrated that the proposed project will not result in the unnecessary duplication of existing hospital services or approved health service capabilities or facilities. Therefore, the application is conforming with this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII, Table VII-1, page 99, 2017 Proposed Staffing for C-Section Suite, the applicant provides the proposed staffing pattern for the C-Section Suite and related services:

2017 Proposed Staffing

Position	FFY 2017 # of FTE Positions	FFY 2017 Salary Per FTE Position
C-Section O.R.		
RN	1.0	$57,964
Scrub Tech	1.0	$34,778
First Asst.	1.0	$41,734
CRNA	1.0	$162,298
Surgical Services Administration		
Director of Surgery	0.2	$92,742
Clerical/Biller	1.0	$28,982
Pre/Post Operative Services		
Pre-Op RN	1.0	$57,964
Post-Op RN	1.0	$57,964
Operating Room		
Perioperative Asst.	1.0	$23,185
Central Sterile Tech.	1.0	$28,982
Nursery and Post-Partum Beds		
RN	11.0	$52,167
Aide	1.5	$28,982
Total	**21.7**	

In Section VII.3(a), page 101 of the application, the applicant states, *"The proposed project will not establish any new positions."* In Section VII.6(a) and (b), page 102 of the application, the applicant states: *"MedWest-Harris has a lengthy set of procedures for recruiting nursing and non-nursing staff. Some of these procedures include: job postings on the WestCare System website; Advertising in professional journals, and job posting web sites and Recruiters."*

The applicant indicates that the administrative personnel, support personnel, and physician staff are currently in place to meet the needs of the proposed project. In Section VII.8 (a), pages 103-104 of the application, the applicant states that David Thomas, M.D. (Radiation Oncologist) will serve as the Chief of Staff and Medical Director. Exhibit 15 contains a support letter from Dr. Thomas. A table on page 104 shows the breakdown of the 91 active medical staff at MedWest-Harris Hospital, by specialty. The applicant adequately demonstrates the availability of resources, including health manpower and administrative personnel for the proposed services. Therefore, the application is conforming with this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Exhibit 3 contains a letter from MW-H's CEO documenting that MW-H currently has all the necessary ancillary and support services available. In Section V.2 (a) the applicant states:

> *"As a healthcare facility that has served the community for nearly 90 years, MedWest-Harris has established relationships with other healthcare providers in the region. MedWest-Harris routinely transfers to and receives patients from other facilities in the area. Specifically, MedWest-Harris is affiliated with the Carolinas Healthcare System and is a member of the Western North Carolina Health Network. Further, because of EMTALA requirements, any patient appropriately transferred for medical care must be accepted by the receiving hospital. Therefore, written transfer agreements are not necessary. Please see Exhibit 14 for a copy of the EMTALA transfer policy."*

Exhibit 26 contains 16 letters of support from physicians and thirteen letters from community residents and local elected officials expressing support for the proposed project and/or an intent to refer patients to MedWest-Harris Women's and Children's services. MW-H adequately demonstrates the availability of the necessary ancillary and support services and that the proposal will be coordinated with the existing health care system. Therefore, the application is conforming with this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of

operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI, page 118, the applicant proposes 900 square feet of new construction on the third floor for a new C-Section suite and 15,705 square feet of relocation and renovation of spaces in the existing Women's and Children's service on the third floor. MW-H is a 177,235 square foot hospital. Upon completion of this project MW-H will have a total of 178,135 square feet of space. In Exhibit 22, the architect certifies that the construction cost for the C-Section suite will be $1,290,000, the relocation and renovation of existing spaces on the third floor will cost $1,396,000, plus a contingency cost of $340,000 for a construction contract cost of $3,026,000. This amount is reflected in the Project Capital Cost Table, Part B., page 106, Construction Contract. Further, the Architect and Engineering fees will be $475,000. Reimbursables are estimated at $6,000. In Section XI.7, pages 120-122, the applicant states that applicable savings features will be incorporated into the construction plans. The applicant states the following:

"*The proposed project has been designed with the intention of improving energy efficiency and water conservation at MedWest-Harris in the following ways:*

- *Architecture: The 900 square foot addition on the third floor will use building insulation that complies with the current energy codes.*
- *Plumbing: While the plumbing in this project is connecting to existing domestic water heating piping serving the area of work, leaving no opportunity to improve energy costs, the architects have chosen to use low shower heads that will*

effectively reduce hot water consumption for those devices, in addition to conserving total water usage for the entire facility.

- *Electrical: The project will connect to existing electrical infrastructure. The project is replacing all the existing lighting with new LED lighting fixtures (plus a few energy efficient CFL fixtures) which will significantly reduce energy consumption.*
- *Mechanical: HVAC system controls will be set utilizing the recommendations from ASHRAE 90.1-2010 for supply temperature and static pressure reset."*

The applicant adequately demonstrated that the cost, design, and means of construction are reasonable, and that the construction cost will not unduly increase costs and charges for the proposed services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.2 of the application, the applicant states that it does not discriminate on the basis of race, sex, creed, age, religion, national origin, handicap or ability to pay. Exhibit 16 contains a copy of MedWest-Harris' Financial Assistance Program Policy. Further, in FY 2012, the most recent full year of available data, MW-H states it provided $15,884,821, or 6.3% of gross revenue, in charity care and bad debt. The following tables, based on Section VI.12 & 13 of the application, show the current FFY2012 patient days as a percent of total utilization by payor source for the entire hospital and for Post-Partum beds and births:

FFY 2012 Payor Mix - as a Percent of Total Patient Days

Payer Category	**Percent of Total**
Commercial	25.3%
Medicare	43.5%
Medicaid	19.9%
Self Pay/Other*	11.2%
Total	**100.0%**

*Other includes Workers Comp and other government Payers.

FFY2012 Post-Partum Bed Payor Mix - as a Percent of Patient Days

Payer Category	Percent of Total
Commercial	24.8%
Medicare	0.3%
Medicaid	72.4%
Self Pay/Other*	2.5%
Total	**100.0%**

FFY2012 Current Births (Vaginal and C-Section) Payor Mix
As a Percent of Total Utilization

Payer Category	Percent of Total
Commercial	24.8%
Medicare	0.3%
Medicaid	72.4%
Self Pay/Other*	2.5%
Total	**100.0%**

The applicant demonstrates the facility currently provides adequate access to medically underserved populations. Therefore, the applicant is conforming with this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints filed against the applicant;

C

In Section VI.10 (a), page 93 of the application, the applicant states *"No complaints have been filed against any affiliated entity of MedWest-Harris regarding civil rights equal access in the last five years."* The applicant is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Application Section VI.2, the applicant states it provides services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay. Exhibit 16 contains a copy of the MW-H Financial Assistance Program Policy. In Section VI.15, the applicant projects the payer mix for the proposed services in FFY 2017, second year following completion of the project. The applicant projects no change in the payor mix for each service component of the project.

The applicant adequately demonstrates that medically underserved persons will have adequate access to its services and is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

See Section VI.9 (a)-(d), pages 92-93 of the application. The applicant offers the following range of means by which patients will have access to the services offered:

- Referrals from physicians who have admitting privileges at the hospital,
- Admissions through the emergency room, and
- Referrals from community agencies that refer through a physician with admitting privileges to the hospital.

The applicant adequately demonstrates that the medically underserved population will continue to have adequate access to the applicant's existing and proposed services and is therefore conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1 (a), (b) and (c), page 80, the applicant states:

"MedWest-Harris is the only acute care facility in Jackson County, and as such will continue to work with the health professional training programs already aligned with the facility. The following schools currently have access to MedWest-Harris for health professional training purposes:

- *Western Carolina University (Nursing)*
- *Southwestern Community College (Allied Health)*

Please see Exhibit 13 for these clinical training agreements. MedWest-Harris is supportive of clinical education; therefore, the hospital's existing services as well as the proposed dedicated C-section room, will continue to be available as clinical sites for training programs."

The applicant adequately demonstrated that MW-H will continue to accommodate the clinical needs of health professional training programs in the area and therefore, the application is conforming with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

WestCare, Inc. d/b/a MedWest-Harris (MW-H) proposes to develop one dedicated C-Section operating room on the third floor of its hospital in Sylva. The hospital has 6 shared operating rooms (one of which services as a C-Section room) and 1 endoscopy procedure room located on the first floor in the hospital's existing surgical suite. The applicant is proposing to develop one dedicated C-Section operating room and related support areas in 900 square feet of new construction on the third floor of the hospital. Further, MW-H proposes that 15,705 square feet of existing space on the third floor will be renovated for Women's and Children's inpatient services.

The MW-H's primary service area is Jackson County. The secondary service area includes Swain, Macon, Graham and Haywood counties.

In Section 1.12, page 12 the applicant states that: MedWest-Harris does not own or operate any other licensed healthcare facilities. For informational purposes, the following table lists the acute care hospitals in the primary and secondary service areas, providers of labor and delivery services, as well as healthcare facilities that are owned and operated by MedWest-Harris' parent company, MedWest Health System.

Name & Location	Location	Description
Primary Service Area		
MedWest-Harris Hospital	Jackson County	86 bed, not-for-profit acute care hospital including Labor & Delivery.
Harris Medical Park	Jackson County	17 physicians in four practices, including radiology, laboratory and outpatient pre-admission services.
Secondary Service Area		
MedWest-Haywood	Haywood County	189 bed public acute care hospital, including Labor & Delivery.
MedWest Health and Fitness Center	Haywood County	Health and fitness center.
MedWest Outpatient Care Center	Haywood County	
The Homestead	Haywood County	Inpatient Hospice facility
MedWest-Swain	Swain and Graham Counties.	48 bed Critical Access Hospital. No Labor & Delivery.
Swain Medical Park	Swain County	Retail pharmacy, Hospital Hill pharmacy, rehabilitation services, pain services and pediatric practice.

In Section V. 7, pages 84- 86, the applicant indicates how development of a C-Section room and renovation of Women's and Children's services will foster quality, access, and cost-effectiveness, as follows:

> "*MedWest- Harris has made a long-term commitment to providing quality care to its patients as demonstrated by its Quality Assessment and Performance Improvement Plans as well as its Utilization and Risk Management Plans included in Exhibits 5, 6, and 7. As the hospital renovates and modernizes its services, MedWest-Harris maintains the importance of continuous quality monitoring. Each service is subject to review under the existing policies.*
>
> *The proposed project will serve to improve the quality of acute care services provided within the hospital. At present, MedWest-Harris provides exceptional services. However, the distance that laboring mothers must travel for C-Section services is less than ideal. In addition, the proposed renovations will allow for greater patient comfort and safety, as described in Section II.1.*

Access Basic Principles

The proposed project will improve access to women's and children's services in the service area, particularly dedicated C-Section services. MedWest-Harris has historically provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay as demonstrated in Exhibit 16….

The proposed project is indicative of MedWest-Harris' commitment to containing healthcare costs and maximizing healthcare benefit per dollar expended. As discussed in Section III.3, MedWest-Harris carefully considered the design of the proposed renovation in order to contain costs and minimize renovation."

In Section V. (7), page 84 the applicant states:

"*The proposed project will foster competition by promoting value, safety and quality, and access to services in the proposed service area and thus will be in compliance with the spirit and legislative intent of the CON Law."*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to establish a dedicated C-Section room on the third floor of MW-H and that it is a cost-effective alternative;
- The applicant adequately demonstrates that MW-H will continue to provide quality services; and
- The applicant demonstrates that MW-H will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

MW-H Hospital is accredited by the Joint Commission on Accreditation of Health Care Organizations and certified for Medicare and Medicaid participation. According to the files in the North Carolina Department of Health and Human Services, Division of Health Service Regulation-Acute and Home Care Licensure and Certification Section, no incidents occurred,

within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming with this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application submitted by MW-H Hospital is conforming with applicable Criteria and Standards for Surgical Services and Operating Rooms as promulgated in 10A NCAC 14C .2100. The specific criteria are discussed below.

.2100 – CRITERIA AND STANDARDS FOR SURGICAL SERVICES AND OPERATING ROOMS

10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:

(1) gynecology;
(2) otolaryngology;
(3) plastic surgery;
(4) general surgery;
(5) ophthalmology;
(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

-NA- On page 26 MedWest-Harris states it is not proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(b) An applicant proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall provide the following information:

(1) the number and type of operating rooms in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area, (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each facility which the applicant or a related entity owns a controlling interest in and is located in the service area after completion of the proposed project and all previously approved projects related to these facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (b) (1) and (b) (2) of this Rule;

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (b) (1) and (b) (2) of this Rule;

(5) a description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

(6) the hours of operation of the proposed new operating rooms;

(7) if the applicant is an existing facility, the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in the facility during the preceding 12 months and a list of all services and items included in the reimbursement;

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility and a list of all services and items included in the reimbursement; and

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

-NA- The applicant is not proposing to increase the number of operating rooms in a service area, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(c) An applicant proposing to relocate existing or approved operating rooms within the same service area shall provide the following information:

(1) the number and type of existing and approved operating rooms in each facility in which the number of operating rooms will increase or decrease (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(2) the number and type of operating rooms to be located in each affected facility after completion of the proposed project and all previously approved projects related to these

facilities (separately identifying the number of dedicated open heart and dedicated C-Section rooms);

(3) the number of inpatient surgical cases, excluding trauma cases reported by Level I, II, or III trauma centers, cases reported by designated burn intensive care units, and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases performed in the most recent 12 month period for which data is available, in the operating rooms in each facility listed in response to Subparagraphs (c) (1) and (c) (2) of this Rule;

(4) the number of inpatient surgical cases, excluding trauma cases reported by level I, II, or III trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and dedicated C-section rooms, and the number of outpatient surgical cases projected to be performed in each of the first three operating years of the proposed project, in each facility listed in response to Subparagraphs (c) (1) and (c) (2) of this Rule;

(5) a detailed description of and documentation to support the assumptions and methodology used in the development of the projections required by this Rule;

(6) the hours of operation of the facility to be expanded;

(7) the average reimbursement received per procedure for the 20 surgical procedures most commonly performed in each affected facility during the preceding 12 months and a list of all services and items included in the reimbursement;

(8) the projected average reimbursement to be received per procedure for the 20 surgical procedures which the applicant projects will be performed most often in the facility to be expanded and a list of all services and items included in the reimbursement; and

(9) identification of providers of pre-operative services and procedures which will not be included in the facility's charge.

- NA- The applicant is not proposing to relocate existing or approved operating rooms within the same service area. The applicant is proposing to establish a dedicated C-Section room.

(d) An applicant proposing to establish a new single specialty separately licensed ambulatory surgical facility pursuant to the demonstration project in the 2010 State Medical Facilities Plan shall provide:

(1) the single surgical specialty area in which procedures will be performed in the proposed ambulatory surgical facility;

(2) a description of the ownership interests of physicians in the proposed ambulatory surgical facility;

(3) a commitment that the Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid surgical cases shall be at least seven percent of the total revenue collected for all surgical cases performed in the proposed facility;

(4) for each of the first three full fiscal years of operation, the projected number of self-pay surgical cases;

(5) for each of the first three full fiscal years of operation, the projected number of Medicaid surgical cases;

(6) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the self-pay surgical cases to be served in the proposed facility, i.e. provide the projected Medicare allowable amount per self-pay surgical case and multiply that amount by the projected number of self-pay surgical cases;

(7) for each of the first three full fiscal years of operation, the total projected Medicare allowable amount for the Medicaid surgical cases to be served in the facility, i.e. provide the projected Medicare allowable amount per Medicaid surgical case and multiply that amount by the projected number of Medicaid surgical cases;

(8) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of self-pay surgical cases;

(9) for each of the first three full fiscal years of operation, the projected revenue to be collected from the projected number of Medicaid surgical cases;

(10) for each of the first three full fiscal years of operation, the projected total revenue to be collected for all surgical cases performed in the proposed facility;

(11) a commitment to report utilization and payment data for services provided in the proposed ambulatory surgical facility to the statewide data processor, as required by G.S. 131E-214.2;

(12) a description of the system the proposed ambulatory surgical facility will use to measure and report patient outcomes for the purpose of monitoring the quality of care provided in the facility;

(13) descriptions of currently available patient outcome measures for the surgical specialty to be provided in the proposed facility, if any exist;

(14) if patient outcome measures are not currently available for the surgical specialty area, the applicant shall develop its own patient outcome measures to be used for monitoring and reporting the quality of care provided in the proposed facility, and shall provide in its application a description of the measures it developed;

(15) a description of the system the proposed ambulatory surgical facility will use to enhance communication and ease data collection, e.g. electronic medical records;

(16) a description of the proposed ambulatory surgical facility's open access policy for physicians, if one is proposed;

(17) a commitment to provide to the Agency annual reports at the end of each of the first five full years of operation regarding:

- *(A) patient payment data submitted to the statewide data processor as required by G.S. 131E-214.2;*
- *(B) patient outcome results for each of the applicant's patient outcome measures;*
- *(C) the extent to which the physicians owning the proposed facility maintained their hospital staff privileges and provided Emergency Department coverage, e.g. number of nights each physician is on call at a hospital; and*
- *(D) the extent to which the facility is operating in compliance with the representations the applicant made in its application relative to the single specialty ambulatory surgical facility demonstration project in the 2010 State Medical Facilities Plan.*

-**NA-** MedWest-Harris is not proposing to establish a new single specialty separately licensed ambulatory surgical program. The applicant is proposing to establish one dedicated C- Section room.

10A NCAC 14C .2103 PERFORMANCE STANDARDS

(a) In projecting utilization, the operating rooms shall be considered to be available for use five days per week and 52 weeks a year.

-C- Under Performance Standards (a), page 39 the applicant indicates that the C-Section room will be available 24 hours per day, 7 days per week and 365 days per year. As such in projecting utilization, MedWest-Harris assumed that the C-Section operating room would be available more than five days per week and 52 weeks per year.

(b) A proposal to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

(1) demonstrate the need for the number of proposed operating rooms in the facility which is proposed to be developed or expanded in the third operating year of the project based on the following formula: {[(Number of facility's projected inpatient cases, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of facility's projected outpatient cases times 1.5 hours)] divided by 1872 hours} minus the facility's total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-section operating rooms or demonstrate conformance of the proposed project to Policy AC-3 in the State Medical Facilities Plan titled "Exemption From Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects;" and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-NA- MedWest-Harris does not currently have an existing or approved dedicated C-Section room nor does the applicant propose a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in an existing facility (excluding dedicated C-Section operating rooms), to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program.

(c) A proposal to increase the number of operating rooms (excluding dedicated C-section operating rooms) in a service area shall:

(1) demonstrate the need for the number of proposed operating rooms in addition to the rooms in all of the licensed facilities identified in response to 10A NCAC 14C .2102(b)(2) in the third operating year of the proposed project based on the following formula: {[(Number of projected inpatient cases for all the applicant's or related entities' facilities, excluding trauma cases reported by Level I or II trauma centers, cases reported by designated burn intensive care units and cases performed in dedicated open heart and C-section rooms, times 3.0 hours) plus (Number of projected outpatient cases for all the applicant's or related entities' facilities times 1.5 hours)] divided by 1872 hours} minus the total number of existing and approved operating rooms and operating rooms proposed in another pending application, excluding one operating room for Level I or II trauma centers, one operating room for facilities with designated burn intensive care units, and all dedicated open heart and C-Section operating rooms in all of the applicant's or related entities' licensed facilities in the service area; and

(2) The number of rooms needed is determined as follows:

(A) in a service area which has more than 10 operating rooms, if the difference is a positive number greater than or equal to 0.5, then the need is the next highest whole number for fractions of 0.5 or greater and the next lowest whole number for fractions less than 0.5; and if the difference is a negative number or a positive number less than 0.5, then the need is zero;

(B) in a service area which has 6 to 10 operating rooms, if the difference is a positive number greater than or equal to 0.3, then the need is the next highest whole number for fractions of 0.3 or greater and the next lowest whole number for fractions less than 0.3, and if the difference is a negative number or a positive number less than 0.3, then the need is zero; and

(C) in a service area which has five or fewer operating rooms, if the difference is a positive number greater than or equal to 0.2, then the need is the next highest whole number for fractions of 0.2 or greater and the next lowest whole number for fractions less than 0.2; and if the difference is a negative number or a positive number less than 0.2, then the need is zero.

-NA- MedWest-Harris is not proposing to increase the number of operating rooms, excluding a dedicated C-Section room.

(d) An applicant that has one or more existing or approved dedicated C-section operating rooms and is proposing to develop an additional dedicated C-section operating room in the same facility shall demonstrate that an average of at least 365 C-sections per room were performed in the facility's existing dedicated C-section operating rooms in the previous 12 months and are projected to be performed in the

facility's existing, approved and proposed dedicated C-section rooms during the third year of operation following completion of the project.

-NA- MedWest-Harris currently has no dedicated C-Section room at its facility or in its' primary service area. This application, if approved, will result in development of MedWest-Harris' first dedicated C-Section room.

(e) An applicant proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall:

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

(2) demonstrate the need in the third operating year of the project based on the following formula: [(Total number of projected outpatient cases for all ambulatory surgery programs in the service area times 1.5 hours) divided by 1872 hours] minus the total number of existing, approved and proposed outpatient or ambulatory surgical operating rooms and shared operating rooms in the service area. The need is demonstrated if the difference is a positive number greater than or equal to one, after the number is rounded to the next highest number for fractions of 0.50 or greater.

-NA- MedWest-Harris is not proposing to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgery program or to add a specialty to a specialty ambulatory surgical program.

(f) The applicant shall document the assumptions and provide data supporting the methodology used for each projection in this Rule.

-NA- The applicant is proposing to develop its' first dedicated C-Section room. Based upon the <u>*Note:*</u> on page 71 of the 2013 State Medical Facilities Plan, the dedicated C-Section Operating Room and associated cases are excluded from the calculation of need for additional "operating rooms" by the standard methodology; therefore hospitals proposing to add a new operating room for use as a "Dedicated C-Section Operating Room" shall apply for a certificate of need without regard to the need determinations in Chapter 6 of the 2013 SMFP.

10A NCAC 14C .2104 SUPPORT SERVICES

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

-NA- MedWest-Harris is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

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

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

-NA- MedWest-Harris is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility, or a new hospital.

10A NCAC 14C .2105 STAFFING AND STAFF TRAINING

(a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to increase the number of operating rooms in a facility, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify, justify and document the availability of the number of current and proposed staff to be utilized in the following areas in the facility to be developed or expanded:

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

-C- Please see Section VII. 2 for proposed staffing for MedWest-Harris' dedicated C-Section room. The table in the section mentioned above addresses the categories (1) through (5). The proposed staffing is based upon MedWest-Harris' years of experience providing C-Section services.

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

-C- MedWest-Harris has 91 physicians on staff as shown in Section VII. Of these physicians, three specialize in obstetrics and gynecology. Reference Exhibit 10 for WestCare Medical Staff Bylaws Credentialing procedures.

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

-C- MedWest-Harris is an acute care hospital and, as such, all physicians practicing at the facility will be members of the MedWest-Harris medical staff. Please see Exhibit 3 for a letter from Steve

Heatherly, Chief Executive Officer of MedWest-Harris, stating that physicians practicing at the medical center are in good standing.

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

-NA- MedWest-Harris is not proposing to develop a single specialty demonstration project.

10A NCAC 14C .2106 FACILITY

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

-NA- MedWest-Harris is not proposing to establish a licensed ambulatory surgical facility that will be physically located in a physicians office, dentist's office or within the general acute care hospital.

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

-NA- MedWest-Harris is not proposing to establish a licensed ambulatory surgery facility or a new hospital.

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

-C- The proposed dedicated C-Section room will have a physical environment that conforms with all applicable regulations for existing facilities. Please reference Exhibit 3 for a letter from the Chief Executive Officer of MedWest-Harris, documenting that the facility conforms, and the new construction will conform, to the requirements of federal, state, and local regulatory bodies.

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

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

-NA- MedWest-Harris is not proposing to establish a new ambulatory surgical facility, a new campus of an existing facility or a new hospital.

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

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

-NA- MedWest-Harris is not proposing to expand by converting a specialty ambulatory surgical program to a multispecialty ambulatory surgery program or proposing to add a specialty to a specialty ambulatory surgical program that does not propose to add physical space to the existing ambulatory surgical facility.