

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: April 25, 2013

PROJECT ANALYST: F. Gene DePorter

SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: K-10061-12/ DLP Maria Parham Medical Center/ Acquire CT simulator by purchasing upgrades for existing CT scanner and software for existing linear accelerator/ Vance County

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, operating rooms, or home health offices that may be approved.

NA

Duke LifePoint Maria Parham Medical Center, LLC d/b/a DLP Maria Parham Medical Center (DLP Maria Parham) proposes to acquire upgrades for an existing CT scanner, and software for its linear accelerator, that will permit the CT scanner to function as a CT simulator for its Radiation Therapy program. While linear accelerators and simulators are subject to CON law, only linear accelerators are regulated by the 2012 State Medical Facilities Plan. Treatment planning through CT simulation is a component of Radiation Therapy services. The applicant does not propose to increase the number of licensed beds in any category, add services, or acquire equipment for which there is a need determination in the 2012 State Medical Facilities Plan (SMFP). DLP Maria Parham shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict, DLP Maria Parham shall materially comply with the last-made representation.

- (2) Repealed effective July 1, 1987.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.

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DLP Maria Parham proposes to acquire upgrades for an existing CT scanner, and software for its linear accelerator, that will permit the CT scanner to function as a CT simulator for its Radiation Therapy program. Thus, upon completion of this project DLP Maria Parham will be capable of providing CT simulation for treatment planning which is an essential component of Radiation Therapy services.

Population to be Served

DLP Maria Parham is located in Henderson and serves a five county Linear Accelerator service area of Vance, Warren, Granville, Durham, and Person, referred to as the North Carolina Medical Facilities Planning Linear Accelerator Service Area 16. More than 90% of DLP Maria Parham Radiation Therapy patients come from the three eastern counties of Radiation Therapy Service Area 16: Vance, Warren and Granville.

- Assumption: The applicant states that the CT simulator use patterns will remain the same through 2016.

In this Section the applicant presents their case by establishing a profile of the proposed service area based upon the following:

- The applicant adjusted Linear Accelerator Service Area 16 geography from five counties to three counties as noted above,
- Table III.1, Section III, page 56, the applicant provides the 2012 through 2016 trend in population growth ,
- Table III. 2, Section III, page 57, DLP Maria Parham Medical Center Provides the historic cancer case incidence of cancer cases for Linear Accelerator Service Area 16 counties to establish patient origin,
- Table III. 3, Section III, page 58, DLP Maria Parham Oncology Center indicates cancer cases by county for 2009 through 2012,
- Table III. 4, Section III, page 59, DLP Maria Parham Oncology Center provides patient origin for operating years 2009 and 2012 that are used to calculate the compound average annual growth rate (CAGR) per service area county,
- Table III. 5, Section III, page 59, DLP Maria Parham calculates CAGRs for the three county adjusted Service Area 16 for 2013 through 2016 to calculate new cancer cases, and
- Determination of the historic, interim, and projected, number of cancer cases in Linear Accelerator Service Area 16 [Durham and Person Counties excluded and Granville, Vance and Warren retained] as shown in the following three tables.

Population growth will average 0.08% per year and the incidence of new cancer cases is projected to show a steady annual growth rate of 9.00% per year. The three counties listed in the following tables show that there will be an additional 1,087 new cancer cases between 2013 and 2016 [Reference Table 10, page 13].

- *Assumption:* Based upon five most recent years of reported cases, the incidence of new cancer cases is growing in each of the three eastern counties in Linear Accelerator Service Area 16 based upon applying each county's Compound Average Annual Growth Rate for new cases.

In Section III.4 (a), page 63, the applicant provides the current patient origin for the inpatients served in the DLP Maria Parham Medical Center, Inc. The inpatient origin for FY 10/1/10-9/30/11 is summarized below:

Table 1
DLP Maria Parham Hospital
Inpatient Discharges [FY10/1/10-9/30/11]

County	# of Patients	% of Total
Vance	3,082	57.04%
Warren	1,388	25.69%
Granville	325	6.02%
Other*	608	11.25%
Total	5,403	100.00%

*Includes: Bladen, Caldwell, Caswell, Dare, Durham, Franklin, Gaston, Graham, Halifax, Haywood, Hertford, Johnston, Lenoir, Nash, New Hanover, Northampton, Onslow, Orange, Person, Pitt, Richmond, Wake, Wayne and Yadkin Counties and other states. Source: NC 2012 Renewal Application for Hospitals.

In Section III.4 (b), page 64, the applicant provides the FY 2011 Radiation Therapy Patient Origin data for Radiation Therapy Patient Origin for DLP Maria Parham Oncology Center. The updated patient origin for FY 2011 Radiation Therapy is shown in the following table:

Table 2
DLP Maria Parham Radiation Therapy
FY 2011 Patient Origin
[FY 10/1/10 to FY 9/30/11]

County	# of Patients	% of Total
Vance	131*	58.4%
Warren	40	17.8%
Granville	32	14.0%
Other	22	9.8%
Total	225	100.00%

Source: 2012 NC License Renewal Application for Hospitals. Based upon 2011 data.

*Other includes: Northampton and other states.

At the request of CON staff, the applicant was asked to provide 2013 Hospital License Renewal data for its linear accelerator. The applicant submitted the following data in Table 2(a):

Table 2(a)
DLP Maria Parham Radiation Therapy
FY 2012 Patient Origin [FY 10/1/11-9/30/12]

County	# of Patients	% of Total
Vance	126*	53.62%
Warren	38	16.17%
Granville	35	14.89%
Other:		15.32%
Franklin	8	
Halifax	4	
Virginia	24	
Total	235	100.00%

Source: 2013 NC License Renewal Application for Hospitals. Based upon 2012 data.

*Other includes: Halifax, Franklin and Virginia.

The applicant states the following in support of revised Table 2(a):

- *As shown above in revised Table 2(a), in FY 2012 that based upon Table 2(a) 84.7% of patients are from the counties of Vance, Warren, and Granville. In CON application's utilization forecast, fewer in-area patients are offset by more out-of-area.*
- *During the period 2007 through 2012, the average proportion of patients from Virginia was variable and represented 8 to 12 percent of patients during the five year period.*
- *The number of simulation procedures required for the project to break even [sic] is 310 to 312. See Proformas (Net Revenue per procedure / Expense/procedure). If the CON utilization methodology used a Maria Parham market share of projected primary service area cancer cases as low as 25.3 percent, it would produce 327, 335, and 342 simulation procedures in Years 01, 02, and 03 respectively. All would be above breakeven."*
- *In fact, new cancer patients at Maria Parham have been trending up as shown in the following table:*

DLP Maria Parham
New Cancer Patients Compound Annual Growth Rate
2007 Through 2016

CAGR	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
13%	129	182	202	236	225	235	265	299	337	380

- *Thus historical and current trends at Maria Parham indicate that forecasts of patients in the CON application are reasonable.*

- *The 2013 LRA patient count does not affect simulations per patient or other program metrics. Simulations were estimated at $(320/225=1.422)$ (page 80). Thus forecasts of simulation procedures in the application are reasonable.*

In Section III.5(c), page 66, the applicant provides the projected Radiation Therapy patient origin percentage by county to be the same for operating year one (1/1/2014-12/31/2014) and year two (1/1/2015-12/31/2015).

Table 3, shows the projected Radiation Therapy Center Patients for project years 2014 and 2015 based upon determining the Radiation Therapy Patient Origin for 2011 (Section IV, page 73). The applicant carried the 2011 county volumes forward to 2014 and 2015.

Assumption: The patient use patterns will remain the same through 2016):

Table 3
DLP Maria Parham Oncology, LLC
Projected Radiation Therapy Center Patients
FY 1/1/14-12/31/15

County	Project Year 1 1/1/14-12/31/14	Project Year 2 1/1/15-12/31/15	Percent of Total
Vance	126	126	53.61%
Warren	38	38	16.20%
Granville	35	35	14.89%
Other*	36	36	15.31%
Total	235	235	100.00%

*Other; Franklin and Halifax counties which are not part of Service Area 16 and Virginia.

The applicant adequately identified the population to be served.

Need for the CT Simulator

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

“The need for the project is driven by the increasing number of cancer patients in the service area, the absence of radiation therapy simulation capability in the service area, and the desire to offer a timely and convenient way to provide simulation to patients prior to commencing Radiation Therapy at DLP Maria Parham.”

The applicant provides a 4 step process for quantifying the need for a CT simulator capability at DLP Maria Parham Medical Center, as follows:

Step 1-Determination of the historic, interim, and projected, number of cancer cases in Linear Accelerator Service Area 16 [Durham and Person Counties excluded and Granville, Vance and Warren retained] as shown in the following three tables:

Table 4
Incidence of Historic Cancer Cases for Linear Accelerator Service Area 16
Calendar Years 2005 Through 2009

County	2005	2006	2007	2008	2009
Granville	326	296	340	333	330
Vance	220	234	244	246	266
Warren	110	116	145	120	129
TOTAL Cancer Cases	656	646	729	699	725
Market Share Percentage	34%	35%	37%	35%	38%
DLPMP Cases	223	226	270	245	276

Source: N.C State Center for Health Statistics and N.C. Central Cancer Registry

Step 2-Estimate the Interim number of cancer cases by adjusted service area counties for the interim years 2009-2013.

Table 5
CY 2009-2013 Interim Cancer Cases for
Adjusted Linear Accelerator Service Area 16

County	2009	2010	2011	2012	2013
Granville	330	306	315	362	395
Vance	266	222	225	269	288
Warren	129	133	138	159	173
TOTAL Cancer Cases	725	661	678	790	856
Market Share Percentage	38%	32%	32%	34%	34%
DLPMP Cases	276	212	217	269	291

Source: North Carolina Central Cancer Registry

The numbers in Tables 5 and 6 have been recalculated. Any differences are do to rounding or a difference of 1-4% or less (differences are not significant enough to change calculation outcomes of future volumes).

Step 3- The applicant then calculated the Compound Annual Average Growth Rate (CAGR) for Granville, Vance, and Warren counties respectively to establish the projected number of cancer cases for 2014 through 2016.

Table 6
CY 2012-2016 Total Projected Cancer Cases for
Adjusted Linear Accelerator Service Area 16

County	2012	2013	2014	2015	2016
Granville	362	395	431	470	512
Vance	269	288	309	330	354
Warren	159	173	188	204	221
Total Projected Cases	790	856	928	1,004	1,087
Market Share Percentage	34%	34%	35%	35%	36%
DLPMP Cases	269	291	325	351	391

Source: North Carolina Central Cancer Registry

The following summary table illustrates the growth in the trend line for actual and projected cancer cases and market share percentage.

The NC Central Cancer Registry publishes annual reports of the incidence of new cancer cases in each county. A retrospective review of the last four year time period (2009-2012) and projected cancer cases from 2013 through 2016 and the compound average annual growth rate for 2013 through 2016 are illustrated in Table 7 below. The applicant's calculations are illustrated in Section III.1 (b), page 59. The Tag column added to the following table shows the CAGR for Granville, Vance and Warren counties.

Table 7
Annual Historic Number of Actual Cancer Cases (2009-2012)
and Projected Number of Annual Cancer Cases (2013-2016)
for Granville, Vance and Warren Counties

County	Historic Annual Incidence of Cancer Cases per 100,000 Population				Projected Annual Incidence of Cancer Cases per 100,000 Population				CAGR 2013-2016
	2009	2010	2011	2012	2013	2014	2015	2016	
Granville	279	306	315	362	395	431	470	512	9.1%
Vance	219	222	225	269	288	309	330	354	7.1%
Warren	124	133	138	159	173	188	204	221	8.6%
3 County Total Cases	622	661	678	790	856	928	1,004	1,087	
Market Share %age of S.A. 16	32%	24.2%	26.4%	35.7%	35.7%	35.7%	35.7%	35.7%	
Projected Market Share Cases		181	203	281	288	295	301	308	

Reported by: NC Central Cancer Registry. Historic (2009-2011) and Projected (2012-2016) Cancer Cases per 100,000 Population.

Note: The projected cases (2014-2016) were calculated using a Compound Annual Growth Rate methodology for 2009-2012, 2013 actual numbers reported by the NC CCR, and 2014-2016 projected cancer cases based upon application of each county's CAGR.

In Section IV.1 (a), page 70 the applicant refers to this application for CT simulation as a "new service." However, developing a simulator capability means adding a single unit or single system of components with related functions. In the recent past Maria Parham has relied on Duke University Hospital Oncology Program to provide simulation service to Linear Accelerator Service Area 16 so they could begin their radiation therapy treatment. As noted elsewhere, in calendar year 2011 the Duke Medical Center Oncology program provided simulation service to 320 individuals who were preparing for radiation therapy at DLP Maria Parham. Each radiation therapy patient will receive approximately 1.4 simulation [320 X 1.4 simulator = 448 simulation studies]. The following table indicates the patient origin for Simulator patients referred to the Duke University Hospital Oncology Program.

In Section IV.1 (d), page 80, Step 10, the applicant indicates that DLP Maria Parham had no historic simulation patients prior to calendar year 2011. Records from Duke University Hospital Oncology Center indicate that 320 CT simulations were conducted in calendar year 2011 on patients referred from Vance County. The referrals to Duke University Hospital received their radiation therapy treatments at Maria Parham. The services received at Duke were simulation only. On average each patient received 1.4 simulations (reference Table 8). Patient origin for simulation closely resembles the Maria Parham acute care inpatient origin.

Table 8
Patient Origin of Simulations Referred from Linear Accelerator Service Area 6
To Duke University Hospital Oncology Program

County	Percent Patients	Number of Patients
Vance	58.4%	187
Warren	17.8%	57
Granville	14.0%	45
Franklin	2.8%	9
Halifax	1.3%	4
Other N.C. and VA.	5.7%	18
Total	100.0%	320

Table 9
DLP Maria Parham Oncology, LLC
Projected Radiation Therapy Center Patients
FY 1/1/14-12/31/15

County	DLP Maria Parham Radiation Therapy Base Year 2011	Project Year 1 1/1/14-12/31/14	Project Year 2 1/1/15-12/31/15	Percent of Total
Vance	131	131	131	58.39%
Warren	40	40	40	17.80%
Granville	32	32	32	14.01%
Other	31	31	31	13.80%
Total	225	225	225	100.00%

In Section IV., page 72, the applicant states:

“Two of the programs in Service Area 16, Duke University Hospital and Durham Regional Hospital, are located in Durham County. According to the 2012 State Medical Facilities Plan, there are nine linear accelerators in Durham County. It is unrealistic to assume that DLP Maria Parham should consider Durham County as part of its service area. Durham County residents are adequately served by hospitals in Durham County.”

Continuing to send patients to Duke University Hospital Cancer Center does not address the following issues; of inconvenience, fatigue, financial hardship and arranging transportation for indigent patients and patients with physical limitations.

In summary, the applicant adequately identified the population to be served and demonstrates the need the population has for the proposed CT simulator. Consequently, 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.

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In Section III.3, pages 62-63, the applicant describes the alternatives considered, including maintaining the status quo, as follows:

1) Status quo would mean continuing to send patients to Duke University Hospital. This would not solve the issues of inconvenience, fatigue, and financial hardship. This approach requires approximately one week between simulation and initiating treatment. Additional treatment delay is currently associated with arranging transportation to Duke for indigent patients and patients with physical limitations.

2) The applicant has a Radiation Therapy Department located in the Oncology Center. This department was considered for conversion of a CT scanner with a CT simulator or conventional simulator. However, there is insufficient space and creating the space would make this project very costly.

3) The preferred alternative is to add additional functionality to an existing CT scanner in the Imaging Services Department. Updating a CT scanner and using it for dual purposes is the least costly alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to the criterion and approved subject to the following conditions:

1. **Duke LifePoint Maria Parham Medical Center, LLC d/b/a DLP Maria Parham Medical Center shall materially comply with all representations made in its certificate of need application and the requested supplemental materials. In instances where the two may conflict, the last made representation governs.**
 2. **Duke LifePoint Maria Parham Medical Center, LLC d/b/a DLP Maria Parham Medical Center 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. **Duke LifePoint Maria Parham Medical Center, LLC d/b/a DLP Maria Parham Medical Center shall install and operate upgrades for one CT scanner and software for its linear accelerator to establish one CT simulator for Radiation Therapy done in the Oncology Center in Henderson, North Carolina.**
 4. **Prior to issuance of the certificate of need, Duke LifePoint Maria Parham Medical Center, LLC d/b/a DLP Maria Parham Medical Center 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.

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The construction costs for this project were estimated by a certified architect based on documentation sent to the Radiation Protection Section of the NC Division of Health Service Regulation. Exhibit 28 contains the architect's letter and Exhibit 7 contains bids in support of the architect's letter.

In Section VIII.; PROJECT CAPITAL COST, page 119-120, the applicant projects the total capital cost for the project will be \$373,165, comprised as follows:

Construction Contract	\$ 4,000
Fixed Equipment Purchase/Lease	\$ 279,015
Moveable Equipment	\$ 19,400
Consultant Fees	\$ 50,750
Other	<u>\$ 20,000</u>

Total \$ 373,165

In Section VIII.3, page 121, the applicant states that the capital cost will be financed with the accumulated reserves of DLP Maria Parham Hospital, LLC. Reference Exhibit 29 for a letter from the hospital Chief Finance Officer indicating that up to \$500,000 will be available to complete this project. In Section IX, page 126, the applicant states there will be no start up or initial operating expenses.

Exhibit 29 of the application contains a November 15, 2012 letter from the Senior Vice President, Chief Financial Officer and Treasurer for DLP Maria Parham that states;

“This letter is to confirm that Maria Parham Medical Center plans to utilize cash reserves to fund the proposed addition of a Computer Tomography Simulator to DLP Maria Parham Medical Center, LLC. DLP Maria Parham has cash reserves of \$6.7m. As Chief Finance Officer, I have the authority to obligate funds up to \$0.5 million to finance the proposed CT Simulator addition.”

Exhibit 26 contains audited financial statements for DLP Maria Parham Hospital which documents the applicant had total net assets of \$93,261,476 million and cash and cash equivalents of \$6,743,941 million as of September 30, 2012. The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In the Statement of Revenues and Expense (Tab-Performa’s) for the entire facility (Form B) and the Statement of Revenues and Expenses for Each Service Component in the Proposed Project (Form C) the applicant projects positive net income from operations in each of the first three years of operation as illustrated in the following table:

Table 10
Projected Net Income for DLP Maria Parham Oncology Center

	Fiscal Year 1/1/14-12/31/2014	Fiscal Year 1/1/15-12/31/15	Fiscal Year 1/1/16-12/13/16
Revenue	\$391,293	\$408,558	\$426,177
Costs	\$261,427	\$267,510	\$273,773
Net Income	\$129,866	\$141,048	\$152,403

The projected costs and revenues are based on reasonable assumptions, including projected utilization. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges and 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.

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In Section III. 1(a), page 55, the applicant provides the following specific statement of unmet need in the proposed service area:

“The need for this project is driven by the increasing number of cancer patients in the service area, the absence of radiation therapy simulation capability in the service area, and the desire to offer a timely and convenient way to provide simulation to patients prior to their commencing Radiation Therapy at DLP Maria Parham.”

The applicant is located in Vance County, one of the five counties that constitute Linear Accelerator Service Area 16 (Durham, Granville, Person, Vance and Warren Counties). Two of the counties (Durham and Person) do not utilize the oncology service capabilities at DLP Maria Parham. There are nine accelerators in Durham County (Duke University Hospital-8 and Durham Regional Hospital-1) DLP Maria Parham has not provided oncology services to residents from Person County in the last year. Therefore, by default, the DLP Maria Parham Medical Center Oncology Service Program is the primary provider of oncology service in the modified service area of Granville, Vance and Warren counties. The following is a summary table that forecasted new cancer cases for these three counties:

Table 11
Projected Annual Population Growth and New Cancer Cases
For Granville, Vance and Warren Counties 2012-2016

County Population Projection and Cancer Case Incidence	2012	2013	2014	2015	2016
Granville Cancer Case Incidence	362	395	431	470	512
Vance-Cancer Case Incidence	269	288	309	330	354
Warren Cancer Case Incidence	159	173	188	204	221
S.A. 16-Total Population	128,097	128,749	129,395	129,043	130,695
S.A. 16- Total New Cancer Cases	790	856	928	1,004	1,087

Sources: DPL Maria Parham Application K-10061-12, Table III.5, Page 59.

N. C. Office of State Management and Budget

Note: NC Central Cancer Registry; Historical and 2012-2013 Projected Cancer Cases.

Application K-10061-12, Table III.5, Page 59; the applicant used a Compound Annual Growth Rate to project growth in new cancer cases from 2014 through 2016.

DLP Maria Parham Medical Center proposes to purchase equipment upgrades for an existing CT scanner, and software for its linear accelerator, that will permit the CT scanner to function as a CT scanner/simulator for Radiation Therapy done in its Oncology Center in Henderson, North Carolina.

See Criterion (3), by reference herein, for additional discussion regarding projected utilization which is incorporated. Based upon the information provided in this section the application is approvable. Therefore, the application is conforming to 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.

In Section VII.1 (a), page 107-108, the applicant provides current and projected staffing of the existing service and proposed CT simulator service located at DLP Maria Parham Hospital. The proposed project requires an additional 0.40 FTE MRI/CT Technologist and an additional 0.3 FTE Radiation Therapist. The applicant states the following:

“DLP Maria Parham has significant experience in the recruitment and hiring of nursing and support staff.”

In Section VII.6, page 112, the applicant describes its experience in the recruitment and retention of staff. In Section VII.8, page 114, the applicant identifies the Chief of Staff/Medical Director for the hospital and an Obstetrics/Gynecology specialist as Medical Director for the DLP Maria Parham Oncology program. The applicant demonstrates the availability of adequate health manpower and management personnel to provide the proposed services and the application is conforming to 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.

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In Section II.2, page 23, the applicant states;

“The necessary ancillary and support services are currently available at DLP Maria Parham and have sufficient capacity to accommodate additional CT services. Reference the letter in Exhibit 11 documenting the availability of staff to support the proposed project.”

In Section V.2(c), page 85, of the application, the applicant provides a list of facilities with which the hospital currently has transfer agreements. In Section V.3 (b), page 86, the applicant references Exhibit 22 for physician letters of support and Exhibit 23 for a listing of providers that have referred to the Radiation Therapy Department from 2008 through September of 2012. The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to 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.

NA

(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;

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In Section VI.12, page 103, the applicant provides the payor mix for “total inpatient days” provided by DLP Maria Parham Medical Center for FY 2011, as shown in the following table;

Table 12
DLP Maria Parham FY 2011 Total Payor Mix for Inpatient Days

Category	Percent of Total Utilization
Self Pay/Indigent/Charity	5.8%
Medicare / Medicare Managed Care	59.8%
Medicaid	20.0%
Commercial Insurance	8.7%
Managed Care	5.7%
Other	0.0%
Total	100%

In Section VI.13, page 104, the applicant provides the payor mix for Radiation Therapy Department services provided by DLP Maria Parham Hospital in FY 2011. The proposed CT simulator will be located in the DLP Maria Parham Imaging Department radiology procedure room (Reference Exhibit 30 for a line drawing of the proposed location). Thus, the applicant assumes the payor mix for the proposed CT simulator will be the same as that for the CT scanner. Eighty-three (83%) of the reimbursement for services is provide through some form government insurance. See the following table;

Table 13
Radiation Therapy Department
FY 2011 Payor Mix
Revenue as a Percent of total Department Revenue

Category	Percent of Total Revenue
Self Pay/Indigent/Charity	3.0%
Medicare	60.6%
Medicaid	8.5%
Managed Care	10.2%
Commercial Insurance	17.1%
Other (Champus, MAP)	0.5%
Total	100.0%

Source: Maria Parham Hospital Files

The applicant demonstrates that medically underserved populations have adequate access to DLP Maria Parham Medical Center’s existing services and the application is conforming to 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 against the applicant;

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In Section VI.10, page 102, the applicant states that no civil rights access complaints have been filed against DLP Maria Parham or any of the facilities comprising Maria Parham in the last five years. Records maintained in the Aspen System indicate that the last posted survey for Maria Parham Hospital was 3/5/2009 in which they received a standard level deficiency for failure to appropriately post signs. The last posted recertification survey occurred on 1/7/2002.

- (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 Section VI.14, page 105, the applicant provides the projected payor mix for “total inpatient” days in the second operating year following project completion, as shown in the following table;

Table 14
Radiation Therapy CT Simulation
Second Full Year of Operation 1/1/2015-12/31/2015
Revenue as Percent of Total Department Revenue

Category	Percent of Total Radiation Therapy Utilization
Self Pay/Indigent/Charity	3.0%
Medicare / Medicare Managed Care	60.6%
Medicaid	8.5%
Commercial Insurance	17.1%
Managed Care	10.2%
Other	0.5%
Total	100%

In Section VI.15(a), page 106, the applicant provides the projected payor mix for Radiation Therapy CT Simulation services in the second operating year following project completion.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed 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

In Section VI.9, page 100, the applicant describes the range of means by which patients will have access to the proposed services. There were 527 referrals to the applicant's Radiation Therapy Department in the 21 month period from January 1, 2011 to September 30, 2012. These referrals were made by 150 providers. The information provided in Section VI.9 is reasonable and credible and supports a finding of conformity with 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

See Section V.1 (a-c), page 84, for documentation that DLP Maria Parham Medical Center will continue to accommodate the clinical needs of area health professional training programs. Currently, Maria Parham Hospital has clinical training program agreements specific to Radiology Technology with Edgecombe Co, Vance-Granville Community College and Pitt Community College. The CT simulator will be available for supervised professional training purposes. See Exhibit 20 for letters of support from professional training programs.

The information provided is reasonable and credible and supports a finding of conformity 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

The applicant adequately demonstrated that the proposal would have a positive impact on the cost effectiveness, quality, and access to the proposed services for the following reasons:

- 1) The applicant currently provides the only oncology services in Vance County. Radiation Therapy is a costly service to provide and maintain. The presence of the Radiation Therapy program at DLP Maria Parham improves geographic access for

patients, reduces travel, improves continuity of care and could positively impact on cost and time for the patient.

2) According to the applicant's payor mix approximately 80% of DLP Maria Parham patients have some or all of their costs covered by Medicare / Medicaid. The applicant demonstrates it will provide adequate access to the proposed services. DLP Maria Parham is the sole hospital in Vance County and provides care to all who seek its services (Reference the Charity Care Policy and the Financial Arrangements Policy in Exhibit 25); and

3) the applicant adequately demonstrates it has and will continue to provide quality CT services. DLP Maria Parham continues meeting the standards of the Joint Commission and other accrediting bodies. DLP Maria Parham maintains its own performance improvement programs (See Section II.7 (a)). Associations with Duke Health Systems, Inc. insure success through application of the most current technologies in patient care [See Criteria (7), (8), and (20)]. Therefore, 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

DLP Maria Parham Medical Center is accredited by the Joint Commission and licensed and certified by the North Carolina Department of Health and Human Services, and certified for Medicare and Medicaid participation. According to the files in the Aspen data base of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, there have been no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to 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

DLP Maria Parham Medical Center proposes to develop a CT simulator for the hospital and Cancer Center. Therefore, the Criteria and Standards for Radiation Therapy

Equipment, promulgated in 10A NCAC 14C .1900, are applicable to this review. The application is conforming to all applicable Criteria and Standards for Computed Tomography Simulation Equipment. The specific criteria are discussed below.

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

.1902(a) *An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.*

-C- DLP Maria Parham is proposing to acquire CT Simulation equipment. DLP Maria Parham has used the Acute Care Facility/Medical Equipment form.

.1902(b) *An applicant proposing to acquire radiation therapy equipment shall also provide the following information:*

(1) a list of all radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;

-C- The applicant proposes to upgrade an existing CT scanner and linear accelerator in order to do CT simulation. The upgrades include:

- Varian software, Workstation, Monitor and Gating System.
- GE Oncology Workstation with simulation, Table Accessories, Laser Lights, and Gating System.
- MedRad Stellant Dual Injector with Overhead Counterpoise, a power injecting system for CT contrast media and saline.

The GE Healthcare CT scanner will use x-ray to measure and image the entire body, as well as sizes, shapes and contours of tumors. The data and images will be stored in the applicant's existing PACS system.

1902(b) *(2) "documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment, each simulator, and any other related equipment proposed to be acquired;"*

-C- The fair market value and purchase price for CT scanner upgrade for simulation purposes is based on bids from three vendors (General Electric, Varian, and MEDRAD). General Electric and Varian pricing is for equipment. The MEDRAD pricing is for software. The Vendors did not respond to all items listed in the following table:

Table 15
DLP Maria Parham Radiation Therapy Department
CT Simulator Upgrade Components by Fair Market Value and Purchase Price

Components	Fair Market Value	Purchase Price
GE Healthcare Laser Lights	Not Provided	\$43,446
GE Healthcare Optima CT580 Oncology Workstation With Full SimMD	\$133,000	\$65,170
GE Healthcare Advantage 4D and Prospective Respiratory Gaiting	\$65,000	\$31,850
GE Healthcare DIACOR RTP Tabletop	\$15,000	\$11,850
GE Total	\$213,000	\$152,316
Varian-Eclipse SV Software	Not Provided	\$25,000
Varian-Non-Calculation Workstation	Not Provided	\$2,998
20" Monitor	Not Provided	\$1,292
Gaiting System for CT	Not Provided	\$71,979
Varian Total	Not Provided	\$101,269
MEDRAD-Stellant Dual Injector	\$38,500	\$25,430

Please reference the equipment quotes in Exhibit 7.

.1902(b) (3) *“the proposed number of patient treatments by intensity modulated radiation treatment (IMRT); Stereotactic radiosurgery; simple, intermediate and complex radiation treatments to be performed on each piece of radiation therapy equipment for each of the first three years of operation following completion of the proposed project and documentation of all assumptions by which utilization is projected;”*

-C- Assumption: Linear Accelerator treatments can be projected using the historic linear accelerator experience and the projected number of CT simulation patients. Based upon this assumption the applicant has provided the following three data tables (Projected Number of Treatments, Projected Number of ESTVs and Projected Simulations) in Section II, pages 33-37 that serve as the basis for responding to this rule:

Table 16
Projected Number of Treatments for the First Three Full Fiscal Years

Treatments	Ratio	Year 1	Year 2	Year 3
		1/1/14-12/31/14	1/1/15-12/31/15	1/1/15-12/31/15
IMRT	22.7%	2,365	2,420	2,475
Stereotactic Radiosurgery	0.0%	0	0	0
Simple	1.4%	144	147	150
Intermediate	0.0%	1	1	1
Complex	50.5%	5,255	5,376	5,498
Field Checks	25.3%	2,633	2,694	2,755
Total	100%	10,397	10,638	10,879

Assumptions:

- The treatment mix of current patients (2011 and 2012) will not change.
- Each radiation therapy patient will have 1.4 simulations, consistent with recent history for DLP Maria Parham patients.
- Simulations will include 20 percent simple and 80 percent complex, based on Maria Parham's history.

Table 17
Projected Number of ESTVs for the First Three Full Fiscal Years

Treatments	ESTV	Year 1	Year 2	Year 3
		1/1/14-12/31/14	1/1/15-12/31/15	1/1/15-12/31/15
IMRT	1	2,365	2,420	2,475
Stereotactic Radiosurgery	1	0	0	0
Simple	1	144	147	150
Intermediate	1	1	1	1
Complex	1	5,255	5,376	5,498
Field Checks	0.5	1,316	1,347	1,377
Total		9,081	9,291	9,501

Table 18
Projected Simulations at DLP Maria Parham
First Three Full Operating Years

Treatment	Year 1 1/1/14-12/31/14	Year 2 1/1/15-12/31/15	Year 3 1/1/16-12/31/16
Simple	93	95	97
Complex	372	380	389

.1902(b) (4) *“Documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days per week;”*

- C- In Section II. (4), page 37, the applicant states that the Radiation Therapy Department at DLP Maria Parham is open Monday through Friday 7:30 to 5:00 pm. The CT simulator will be available from 8:30 am to noon, and 1:00 pm to 5 pm, Monday through Friday.
- .1902(b) (5) *“Document that no more than one simulator is available for every two linear accelerators in the applicant’s facility, except that an applicant that has only one linear accelerator may have one simulator;”*
- C- Currently, the applicant has no simulator capacity. With the approval of this proposal the applicant projects that the simulator equipment will be on campus by 5/11/2013 and operational by 7/1/2013.
- .1902(b) (6) *“Documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;”*
- C- The applicant is an existing North Carolina licensed and Medicare/Medicaid certified hospital with an existing Radiation Therapy Department as well as an existing CT scanner. All existing equipment conforms to federal, state, and local regulatory requirements. The equipment is maintained under warranty and service agreements and there is a contracted physicist who performs all necessary calibrations and shielding measures.
- .1902(b) (7) *“the projected total number of radiation treatment patients by county that will be treated in the facility in each of the first three years of operation following completion of the project;”*
- C- The following table shows projected patient volume for the first three full fiscal years of operation by county of origin.

Table 19
Projected Patient Volume for First Three Full Fiscal Years

County of Origin	Patient Origin From Table III.6	Year 1. 1/1/14-12/31/14	Year 2. 1/1/15-12/31/15	Year 3. 1/1/16-12/31/16
Vance	58.4%	191	195	200
Warren	17.8%	58	60	61
Granville	14.0%	46	47	48
Other	9.8%	32	33	34
Total	100.0%	327	334	342

- 1902(b) (8) *“the projected number of radiation treatment patients that will be treated for palliation in each of the first three years of operation following completion of the proposed project;”*

- C- Approximately 20 % of radiation therapy patients receive therapy for palliation. Reference the following table;

**Table 20
DLP Maria Parham Patients Treated for Palliation**

Palliative Treatment	Year 1 1/1/2014- 12/31/2014	Year 2. 1/1/15- 12/31/2015	Year 3. 1/1/2016- 12/31/2016
Total Number of Patients	327	334	342
% Treated for Palliation	20%	20%	20%
# Treated for Palliation	65	20	21

1902(b) (9) *“the projected number of radiation treatment patients that will be treated for cure in each of the first three years of operation following completion of the proposed project;”*

- C- Approximately 70% of radiation therapy patients receive therapy for cure. The following table illustrates that in Year 1-229 patients will be treated on a cure basis; Year 2-234 patients and Year 3-239 will be treated on a cure basis.

**Table 21
DLP Maria Parham Radiation Department
Patients Receiving Curative Treatments**

Palliation Treatment For Cure	Year 1 1/1/2014- 12/31/2014	Year 2. 1/1/15- 12/31/2015	Year 3. 1/1/2016- 12/31/2016
Total Number of Patients	327	334	342
% Treated for Palliation	80%	80%	80%
# Treated for Palliation	262	272	274

1902(c) (1-15) an applicant applying for a linear accelerator for development of a multidisciplinary prostate health center pursuant to a need determination for a demonstration project in the State Medical Facilities Plan shall provide the following information:

- NA- This application is for CT simulation equipment not preparing for the development of a prostate health center.

10A NCAC 14C .1903 Performance Standards

.1903(a) (1) (a) *“An applicant proposing to acquire a linear accelerator shall demonstrate that performance standards are met.”*

(1) “an applicant’s existing linear accelerator located in the proposed service area shall have performed at least 6,750 ESTV treatments per machine in the twelve months prior to the date an application is submitted.”

-NA- This application is for CT simulation equipment.

.1903(a) *(2) “each proposed linear accelerator shall be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment.”*

-NA- This application is for CT simulation equipment.

.1903(a) *(3) “An applicant’s existing linear accelerators located in the proposed service area shall be projected to be utilized at an annual rate of 6,750 ESTV treatments per machine during the third year of operation of the new equipment.”*

-NA- The application is for CT simulation equipment.

.1903(b) *“A linear accelerator shall not be held to the standards in Paragraph (a) of this rule if the applicant provides documentation that the linear accelerator has been or shall be used exclusively for clinical research and teaching.”*

-NA- This application is for CT simulation equipment.

.1903(c) *(1) “An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:*

The number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence .”

-NA- The applicant is proposing to add CT simulation to an existing Radiation Therapy Department. However, the applicant provided the following utilization projections.

- In the following table the applicant illustrates the number of patients that will be cared for in the first full three years of operation;

**Table 22
Annual Number of Patients for
First Three Full Years of Operation**

First Three Years of Operation	Annual Number of Patients
12/31/14	327
12/31/15	334
12/31/16	342

- The maximum number of simulations that can be done annually is 1,320.
- Current FY 2012 year to date CT scanner volume (9 months) show growth and the year-end volumes on the current single CT scanner is expected to be over 10,000.

.1903(d) *“The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.”*

- C- The applicant estimates that it would be able to do CT simulation 220 days per year, 7.5 hours per day. This assumes that the machine and staff are dedicated exclusively to CT simulation. However, this is not the case. MRI/CT Technology staff and the CT scanner will be shared with other Imaging Services and the CT scanner will be used for diagnostic imaging when not being used for CT simulation. The applicant projected CT simulation volume of one to two simulations per week day. See Section II.8, pages 47-48. The applicant has adequately documented all assumptions and data supporting the methodology used to project utilization.

.1904 SUPPORT SERVICES

.1904(a) *“An applicant proposing to acquire radiation therapy equipment shall document that the following items will be available; and if any item will not be available, the applicant shall provide substantive information obviating the need for that item:*

(1) an organized program for radiation therapy continuing education for radiation therapists, technologists and medical staff.”

- C- Reference Section II.8, page 49 and Exhibit 20, the applicants adequately document that an organized program of radiation therapy continuing education will be provided for radiation therapists, technologists and medical staff.

.1904(a) *(2) “a program for the collection of utilization data relevant to the applicant’s provision of radiation therapy services;”*

- C- Reference Section II.8 (a) (2), page 49, DLP Maria Parham has an active tumor registry on site and participates in the North Carolina Central Cancer Registry. These registries include radiation utilization. The DLP Maria Parham Cancer Center maintains monthly reports of utilization of all radiation therapy services. Simulation will be included in these monthly reports.

.1904(a) (3) Medical Laboratory Services

- C- The applicant is an existing acute care hospital offering clinical medical laboratory and pathology services. See the letter in Exhibit 11 from the hospital's Chief Operating Officer regarding the ability to support the CT simulator. Exhibit 18 contains a letter from the physician who is the AmeriPath Services who provides professional laboratory and pathology services at DLP Maria Parham.

.1904(a) (4) Pathology Services

- C- The applicant is an existing acute care hospital offering clinical medical laboratory and pathology services. See the letter in Exhibit 11 from the hospital's Chief Operating Officer regarding the ability to support the CT simulator. Exhibit 18 contains a letter from the physician who is the AmeriPath Services who provides professional laboratory and pathology services at DLP Maria Parham.

.1904(a) (5) Pharmaceutical Support Services

- C- The applicant is an existing acute care hospital offering pharmaceutical support services. See the letter in Exhibit 11 from the hospital COO, regarding the ability to support the CT simulator.

.1905 STAFFING AND STAFF TRAINING

.1905(a) *"An applicant proposing to acquire radiation therapy equipment shall document the number and availability of staff or provide evidence that obviates the need for staff in the following areas:*

- C -
 - 1) Radiation Oncologist – The Medical Director provides professional services and medical direction and serves full time at DLP Maria Parham and will serve as the Medical Director for the CT simulation service.
 - 2) Radiation Physicists – Radiation Physics is currently provided by ProPhysics. Reference the letter in Exhibit 9. A full time Radiation Therapy physicist is provided under contract with Duke University Health System Inc.
 - 3) Dosimetrist or Physics Assistant – Treatment planning will continue to be performed at Duke University Hospital. The DLP Maria Parham's Chief Radiation Therapists assist the Radiation Oncologists and the Physicist at DLP Maria Parham with Dosimetry and Physics (Reference Exhibit 15 for resume and Exhibit 16 for Job Description).

- 4) Radiation Therapist - The Chief Radiation Therapist and the staff radiation technology therapists are provided to the applicant under a contact with Duke University Health Systems, Inc.
- 5) Radiation Oncology Administrator-The Chief Radiation Therapy Technologists works under contact from Duke University Health System to DLP Maria Parham. He will continue in his clinical administrative capacity. The Director of Home Health, Radiation and medical oncology will continue in this administrative capacity for the entire Oncology Center at DLP Maria Parham.
- 6) Register Nurse or LPN – DLP Maria Parham has one registered nurse in the Oncology Center, Radiation Therapy Department. Duke University Health System provides continuing education related to the care of radiation therapy patients.
- 7) Physical Therapist – Existing hospital staff will provide this service.
- 8) Dietician - Existing hospital staff will provide dietician service.
- 9) Pharmacists – Existing hospital staff will provide this service.
- 10) Social Worker – Existing hospital staff will provide this service.
- 11) Maintenance Engineer – Existing hospital personnel will provide this service.