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Memorandum

To: Commissioners

From: Paul Parker pep

Date: February 16, 2012

Re: Johns Hopkins Bayview Medical Center
Docket No. 11-24-2322

* *

Enclosed is a staff report and recommendation for a Certificate of Need ("CON") application filed by Johns Hopkins Bayview Medical Center ("JHBMC") in Baltimore. The project is development of a comprehensive cancer program facility on the JHBMC campus, centralizing the hospital's oncology/hematology services, which are currently provided in two separate areas of the hospital, and introducing radiation therapy services. The project will involve construction of a new building adjacent to the Bayview Medical Office building the renovation of adjacent space.

The total estimated cost of the project is $26,057,437 and the project will be funded primarily through debt ($19.3 million) and cash ($6.5 million). JHBMC states that it "intends" to seek a rate increase in the future to "help fund this project" but no request for a rate increase has been filed with HSCRC.

This project contains no elements that categorically require CON review and approval. The cost estimate, which is well above the current hospital capital expenditure threshold ($10.95 million) requiring approval, is the only basis for this review. The hospital has chosen to obtain CON approval to make a substantive rate increase request possible but could implement this project without CON approval by "pledging" to limit any rate adjustment to a total of $1.5 million.

IN THE MATTER OF	*	**BEFORE THE**
	*	
JOHNS HOPKINS	*	**MARYLAND HEALTH**
	*	
BAYVIEW MEDICAL CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 11-24-2322	*	
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Staff Report and Recommendation

February 16, 2012

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I. INTRODUCTION

A. The Applicant and the Project

Johns Hopkins Bayview Medical Center, Inc. ("JHBMC") is a 513-bed hospital located in the City of Baltimore at 4940 Eastern Avenue. JHBMC is a not-for-profit corporation and is part of the Johns Hopkins Health System, Inc., which includes three other Maryland general acute care hospitals (The Johns Hopkins Hospital, Howard County General Hospital, and Suburban Hospital, in Montgomery County). The land title for the land constituting the JHBMC campus is held by FSK Land Corporation, an affiliate of JHHS, while the buildings are owned by JHBMC. The facility is primarily a general acute care hospital, with 348 licensed acute care beds. It also holds licenses for 85 special hospital beds (nine medical rehabilitation and 76 chronic care beds) and 80 comprehensive care facility (nursing home) beds.

JHBMC seeks approval for a capital expenditure described as creating a comprehensive cancer program (Cancer Center) in the Bayview Medical Office ("BMO") building. This project includes the construction of an 18,030 gross square foot ("GSF") structure adjacent to the BMO Level 1 and the renovation of adjacent space. See Appendix A for conceptual design drawings of the new construction and renovated space. Inpatient bed capacity is unaffected by this proposal.

This project includes relocating (from the Burton Pavilion) and combining existing oncology/hematology services, consisting of eleven infusion stations and six exam rooms, and the medical infusion clinic (located in BMO Level 1), with eight infusion stations. The project will add two infusion stations and six exam rooms to the new combined infusion suite. The proposed 1,450 SF infusion space accommodates 18 chairs and three stretchers, with a view of a private courtyard. Two private infusion bays and one private infusion room are located directly outside the 250 SF nurses' station. Two 200 SF procedure rooms will be accessed from the Infusion Area for tasks such as bone marrow extraction and lumbar punctures. In addition, the Center will include a new 600 SF oncology pharmacy, which will be located with direct access to and from the infusion area and a 520 SF multi-disciplinary room for patients, faculty, and staff to meet, accessible from the main North-South corridor of the Center.

A new radiation oncology service will be established on the JHBMC campus as a part of this project. Two linear accelerator vaults (only one to be equipped at program start-up) will be constructed and eight new exam rooms, as well as a computed tomography ("CT") simulator will be included. Dosimetry, physics, and information technology support are located in close proximity to the vaults and simulator. Staff offices for the radiation oncology program are located in the south end of the new structure. Six hundred SF of mechanical and electrical space support the new structure. Heating, ventilation, and air conditioning ("HVAC") units will be located on the roof.

The treatment service capacities of the proposed project can be summarized as follows:

Table 1: Current and Proposed Cancer Service Capacity
Johns Hopkins Bayview Medical Center

	Current Capacity	To be Added	Proposed Capacity
Infusion Stations	19	2	21
Exam Rooms	6	14	20
Linear Accelerator Vaults	0	2	2
Linear Accelerators	0	1	1
CT Simulator	0	1	1

Source: Adapted from JHBMC CON Application, page 4.

This project also involves the renovation of 3,000 SF of office space for oncology/hematology physicians and administrative staff in the Administrative Services Center (ASC) to support the expanded cancer program.

The proposed phasing of the project is as follows:

Phase 1: Site work/preparation; renovation of 3,000 SF of office space in ASC building

Phase 2: New 18,030 GSF one story structure to be built including simulator and control room, linear accelerator bunker, 16 exam rooms, 2 procedure rooms, 6 infusion bays, 3 stretcher bays, nurses' station, physician work area, faculty and staff offices, multi-disciplinary room

Phase 3: Interior demolition and renovations of existing BMO space (7,530 GSF, one story), 15 infusion bays, 4 exam rooms, oncology pharmacy, check-in & waiting, nurses' station, physician work area, clinical support areas

Phase 4: Final site work (total site disturbance - 1.1 acres)

The total estimated cost of the project is $26,057,437; $25,772,215 in capital costs and the balance in financing and other cash requirements. JHBMC proposes to fund this project with $19,300,000 in bond sale proceeds, $6,544,525 in cash, and $212,912 in interest income. "JHBMC intends at some time in the future to seek from the Health Services Cost Review Commission ("HSCRC") additional rate charging authority to help fund this project."

This project contains no elements that categorically require CON review and approval. The introduction of radiation therapy services by a health care facility does not require CON review and approval in Maryland. The cost estimate, which is well above the current hospital capital expenditure threshold ($10.95 million) requiring approval, is the only basis for this review. The hospital has chosen to obtain CON approval to make a substantive rate increase request possible but could implement this project without CON approval by "pledging" to limit any rate adjustment to a total of $1.5 million. It is uncertain if JHBMC would qualify for any substantial adjustment in rates by HSCRC for this capital expenditure if a rate adjustment was requested.

B. Summary of Staff Recommendation

Staff recommends approval of the proposed project. The key findings of Staff's review of the proposed project can be summarized as follows:

- JHBMC has demonstrated an institutional need to improve its provision of medical oncology services and the addition of radiation therapy services will enhance its ability to conveniently coordinate oncology services for its patient population;

- JHBMC has demonstrated that the proposed project is a cost effective alternative for meeting its objectives for centralizing cancer care services on its campus and expanding its range of such services;

- JHBMC has documented the availability of sufficient resources to fund the project, as proposed, and its financial projections and assumptions are reasonable. These indicate feasibility of the project and long-term viability of JHBMC; and

- The project will primarily impact the provision of radiation therapy services at a JHBMC affiliate, The Johns Hopkins Hospital, which the applicant believes is approaching capacity use of its facilities for this service. It will increase the cost of delivering services at JHBMC, but this impact is reasonable to obtain the facility and service improvements and operational improvements gained through the expenditure.

JHBMC has indicated that it intends, at some time in the future, to seek approval to increase its charges, to defray the costs of this project. It is uncertain if it would qualify for such consideration.

II. PROCEDURAL HISTORY

A. Review of the Record

On June 3, 2011, JHBMC submitted a Letter of Intent to apply for a Certificate of Need ("CON") for the creation of a comprehensive cancer program. This letter was acknowledged by Commission staff on June 3, 2011 [Docket Item ("DI") #1].

The Hospital filed its CON application on August 5, 2011 (DI #2).

Commission staff acknowledged receipt of the application for the project (DI #3) on August 9, 2011 and requested publication of a notice of receipt of the application in the next issue of the Baltimore Sun (DI #4) and Maryland Register (DI #5).

On August 13, 2011, the Baltimore Sun provided proof of publication of the application notice. (DI #6).

On August 19, 2011, staff requested additional information from JHBMC (DI #7). JHBMC responded to the additional information questions on September 6, 2011 (DI #8).

On September 23, 2011, staff requested publication of a notice of the application's docketing in the next issue of the Maryland Register (DI #9).

On September 27, 2011, staff notified the applicant of docketing and sent additional information questions to JHBMC (DI#10).

On September 26, 2011, Commission staff requested publication of the docketing notice by the Baltimore Sun. (DI #11).

On September 27, 2011, staff requested review and comment on the CON application by the Baltimore City Health Department. (DI#12)

On October 6, 2011, the Baltimore Sun provide proof of publication of the docketing notice. (DI #13).

On October 21, 2011, the applicant requested additional time to respond to questions (DI #14). On October 26, 2011, the applicant responded to the additional questions sent on September 26, 2011 (DI #15).

On January 6, 2011, the applicant provided a corrected version of versions of Table 3 (DI #16).

On January 5, 2011, staff requested comments from HSCRC (DI #17).

On January 27, 2012, following a meeting with HSCRC staff, the applicant provided additional information, including corrected utilization projections and a response to issues raised by HSCRC (DI # 18).

B. Interested Parties

There are no interested parties in this review.

C. Local Government Review and Comment

None.

D. Community Support

JHBMC provided 22 letters of support for this application. These letters were written by:
H. Edward Parker, Chairman, JHBMC Community Advisory Board (representing 21 members)
Ronald Overby, President, Bayview Business Association
Janelle Gwynn, Administrative Director, Chesapeake Gateway Chamber of Commerce
Donna Bethke, President, Overlea-Fullerton Business and Professional Association
Barbara J. Faltz Jackson, President, The Frankford Improvement Association, Inc.
Lynn Richardson, President, Perry Hall/White Marsh Business Association
Tony Dawson, Belair-Edison Community Association
Michael L. McKemy, Home Fuel & Equipment
Michael L. McKemy, Chairman, Board of Directors, Millers Island Edgemere Business Association
Elaine Welkie, Chairperson, Southeastern Neighborhoods Development

Elaine Welkie, President, Bayview Community Association, Inc.
D. Christopher Ryer, Executive Director, Southeast Community Development Corporation
C. Scott Holupka, President, Greater Dundalk Community Council
Lt.Col. John E. Gavrilis, CEO, and Jason Filippou, Executive Director, Greektown Community Development Corporation
Rhonda Crisp, President, & Amy Menzer, PhD, Executive Director, Dundalk Renaissance Corp.
Karen Cruz, President, Eastfield Stanbrook Civic Association
W. Eric Johnson, Pastor, Union Baptist Church
Keith B. Scott, President and CEO, Baltimore County Chamber of Commerce and Small Business Resource Center
Jean P. Pula, President, Hampstead Hill Association (unsigned)
Naomi Benyowitz, Executive Director, HARBEL Community Organization, Inc.
Sharon Luette, President, Dundalk Chamber of Commerce
Reverend Stephen L. Thomas, Sr., Pastor, Zion Baptist Church of Christ (unsigned)

III. BACKGROUND

A. Hospital Service Area and Demographics

COMAR 10.24.10.06(25) defines "primary service area" as "The Maryland postal zip codes from which the first 60% percent of a hospital's patient discharges originate during the most recent twelve month period…" JHBMC indicates that of its total 756 tumor cases in CY2009, 61% of its new cancer cases at the time of diagnosis were from Baltimore City and Baltimore County and 76% of patients were residents of the six localities that make up Central Maryland. A total of 16% of cases in CY2009 were from out-of-state, while the remaining approximately 8% came from other Maryland localities.

As illustrated in the table below, there were slightly more than 1.4 million people residing in Baltimore City and Baltimore County in 2010. Since older adults are more likely to be diagnosed with cancer, it is important to look at this group's representation in the area's population. Those 50+ years represented 32.6% of JHBMC's reported primary service area in 2010, slightly higher than that age group's representation in Maryland as a whole (32.0%), however, those that are 65+ years are a relatively smaller portion of JHBMC's service area than the state as a whole.

Table 2:
2010 Population & Age Distribution - Baltimore City & County, JHBMC Service Area
Age Distribution – Maryland 2010 Population

	Baltimore City	Baltimore County	JHBMC Svc Area Total	% of Total	Maryland % of Total
0-19	155,210	201,053	**356,263**	**25.0%**	**26.3%**
20-34	160,024	161,327	**321,351**	**22.5%**	**20.0%**
35-49	120,136	162,434	**282,570**	**19.8%**	**21.8%**
50-64	112,779	162,739	**275,518**	**19.3%**	**19.7%**
65+	72,812	117,476	**190,288**	**13.3%**	**12.3%**
Total	**620,961**	**805,029**	**1,425,990**	**100.0%**	**100.0%**

Source: US Census, 2010.

The applicant notes that, according to *Market Expert*, those ages 55+ years is forecast to increase 13.9% from 2010 to 2015, compared to an overall population growth of only 1.2% in Central Maryland's overall population.

Based on Census data and as illustrated in the table below, it appears that all the localities in the Baltimore region with the exception of Baltimore City, as well as Maryland overall, have increased in population between 2000 and 2010. While the region saw an increase of 150,000 residents, JHBMC's service area (Baltimore City and County) only increased by a total of about 20,000 people. Projections were not available from the Census Bureau. Therefore, the latest projections from the Maryland Department of Planning were examined. Similar annual percentage changes were projected for most localities, with the exception of Baltimore City which are projected to increase and have actually decreased in population and Howard County which has experienced a significantly higher growth rate than its projected rate. However, it is important to note that the Department of Planning population estimates and projections are not based on the 2010 Census and will likely be updated based on Census findings.

Table 3: Population, 2000 & 2010, Projected 2015 Population
Maryland &, Central Maryland

	Census			MD Dept of Planning		
	2000	**2010**	**% Annual Change**	**2010**	**2015**	**% Annual Change**
MARYLAND	**5,296,486**	**5,773,552**	**0.9%**	**5,774,000**	**6,038,450**	**0.9%**
CENTRAL MARYLAND	**2,512,431**	**2,662,691**	**0.6%**	**2,676,850**	**2,778,350**	**0.7%**
Anne Arundel County	489,656	537,656	1.0%	525,700	546,500	0.8%
Baltimore County	754,292	805,029	0.7%	801,700	830,400	0.7%
Carroll County	150,897	167,134	1.1%	173,100	183,600	1.1%
Harford County	218,590	244,826	1.2%	245,900	258,800	1.0%
Howard County	247,842	287,085	1.6%	285,600	298,800	0.9%
Baltimore City	651,154	620,961	-0.5%	644,850	660,250	0.5%

Source: U.S. Census; MD Department of Planning, November 2010 Update

B. Selected JHBMC and Regional Utilization Trends

As illustrated in the table below, Maryland hospitals, broadly, saw declines in MSGA patients in 2010 after reaching recent-period peaks in 2009. (See pattern of discharges over the last five years for the City, Central Maryland, and the State.) JHBMC and The Johns Hopkins Hospital (JHBMC's closest neighboring hospital) experienced a less volatile path, but 2010 volume was smaller than that experience in 2005.

With 215 MSGA and 34 observation/stepdown beds (a total of 249 beds and 76,385 patient days, JHBMC had an average daily census ("ADC") of 209 patients and an average length of stay ("ALOS") of 4.33 days in 2010. Central Maryland, with 5,246 licensed MSGA beds in 22 hospitals and 1,364,037 patient days, had an ALOS of 4.2 days.

Table 4: MSGA Discharges, 2015-2010
Selected Hospitals

Hospital	MSGA DISCHARGES						
	2005	2006	2007	2008	2009	2010	% Change
Johns Hopkins Bayview	18,114	18,259	17,941	17,557	17,768	17,635	-2.6%
The Johns Hopkins	39,331	35,319	34,394	34,670	34,739	34,108	-13.3%
Baltimore City Hospitals	189,703	188,046	187,945	190,169	194,121	185,900	-2.0%
Central MD Hospitals	327,392	328,944	329,656	337,848	341,305	321,602	-1.8%
All Maryland Hospitals	530,882	534,663	539,085	552,155	554,941	531,986	0.2%

Source: Maryland Health Care Commission

As shown in the following chart, JHBMC reports that it has experienced an annual growth rate of 1% in the number of tumors it registered between 2005 and 2009. It should be noted that there has been significant variability and no sustained growth in overall tumors during that period. However, there has been a significant decrease in prostate cancer cases and excluding those from the totals results in a sustained 6.7% annual growth rate in cases, resulting in an average of approximately 50 new tumors identified per month at JHBMC.

Table 5: Tumor Registry Reports
JHBMC, 2005-2009

Johns Hopkins Bayview Medical Center Tumor Registry

Analytic Primary Sites (Calendar Year)	Actual 2005	Actual 2006	Actual 2007	Actual 2008	Actual 2009	2005-2009 Variance	Annual Growth Rate
Head/Neck	5	14	10	11	13	8	27.0%
Colon/Rectal (all sites)	67	51	86	84	62	(5)	-1.9%
Digestive Other sites	35	33	45	42	57	22	13.0%
Bronchus/Lung	99	94	107	109	103	4	1.0%
Respiratory Other sites	6	4	10	12	8	2	7.5%
Skin	26	34	33	41	32	6	5.3%
Soft Tissue	9	8	2	11	2	(7)	-31.3%
Breast	36	42	56	43	51	15	9.1%
Female Genitalia	19	28	15	15	16	(3)	-4.2%
Prostate	264	211	214	203	158	(106)	-12.0%
Male Genitalia Other sites	8	3	3	4	5	(3)	-11.1%
Brain/CNS	35	46	40	44	75	40	21.0%
Urinary	56	49	67	71	80	24	9.3%
Thyroid & Oth Endocrine	18	29	27	35	14	(4)	-6.1%
Hematopoietic/Leukemia	19	13	20	14	19	-	0.0%
Lymphoma & Hodgkin's	14	19	24	12	38	24	28.4%
Other	1	-	1	9	7	6	62.7%
Unknown & ill defined	9	10	25	15	16	7	15.5%
Total	**726**	**688**	**785**	**775**	**756**	**30**	**1.0%**
Total excluding Prostate	**462**	**477**	**571**	**572**	**598**	**136**	**6.7%**

Source: JHBMC CON Application, 11-24-2322, page 43.

The applicant provided the following information comparing selected Central Maryland hospitals relative to hospital bed size, number of tumors reported to the Maryland tumor registry in 2007 (the latest data available), and whether or not the hospital has radiation therapy. While

there does not appear to be a significant relationship between bed size and number of cancer cases, it appears that many area hospitals comparable to JHBMC have radiation oncology facilities, including some with lower numbers of reported cancer cases. Cancer treatment usually occurs in an outpatient, community-based setting.

Table 6: Tumor Registry Reports
Central Maryland Hospitals, 2007

On-Site Radiation Oncology at Selected Central Maryland Hospitals

Central Maryland Hospitals	2011 Bed License	2007 Tumor Registry	On-Site Radiation Oncology
Greater Baltimore Medical Center	285	1949	Yes
Anne Arundel Medical Center	324	1353	Yes
Sinai Hosital *	424	1327	Yes
Franklin Square Hospital Center	376	1186	Yes
St. Joseph Medical Center	300	1047	Yes
St. Agnes Hospital	314	899	Yes
JHBMC	**348**	**785**	**No**
Baltimore Washington Medical Center	321	747	Yes
Howard County General Hospital	238	463	Yes
Carroll Hospital Center	195	428	Yes
Unon Memorial Hospital **	271	427	Yes
Upper Chesapeake Medical Center	186	419	In Development
Harbor Hospital	193	410	Yes
Good Samaritan Hospital	235	309	Yes

Source: JHBMC CON Application, 11-24-2322, page 46.

IV. STAFF REVIEW AND ANALYSIS

The Commission is required to make decisions on CON applications in accordance with the general Certificate of Need review criteria at COMAR 10.24.01.08G (3) (a) through (f).

A. The State Health Plan

COMAR 10.24.01.08G(3)(a)State Health Plan.
An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The relevant State Health Plan chapter in this review is COMAR 10.24.10, Acute Inpatient Services.

COMAR 10.24.10.04A — General Standards.

> **(1) Information Regarding Charges.** ***Information regarding hospital charges shall be available to the public. After July 1, 2010, each hospital shall have a***

written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

Information regarding hospital charges shall be available to the public. Each hospital shall have a written policy for the provision of information to the public concerning charges for its services. At a minimum, this policy shall include:

(a) Maintenance of a Representative List of Services and Charges that is readily available to the public in written form at the hospital and on the hospital's internet web site;

(b) Procedures for promptly responding to individual requests for current charges for specific services/procedures; and

(c) Requirements for staff training to ensure that inquiries regarding charges for its services are appropriately handled.

JHBMC states that it "…maintains a representative list of services and charges, which is accessible using a link on the JHBMC patient and visitor services webpage" and it is "available by request in written form" and "updated quarterly." Commission staff has confirmed the availability of a list of services and charges on the JHBMC website. Moreover, the applicant provided a copy of JHBMC's policy describing the list's maintenance procedure and training of staff. JHBMC complies with this standard.

(2) Charity Care Policy ***Each hospital shall have a written policy for the provision of charity care for indigent patients to ensure access to services regardless of an individual's ability to pay.***

(a) The policy shall provide:

(i) Determination of Probable Eligibility. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital must make a determination of probable eligibility.

(ii) Minimum Required Notice of Charity Care Policy.

1. Public notice of information regarding the hospital's charity care policy shall be distributed through methods designed to best reach the target population and in a format understandable by the target population on an annual basis;

2. Notices regarding the hospital's charity care policy shall be posted in the admissions office, business office, and emergency department areas within the hospital; and

3. Individual notice regarding the hospital's charity care policy shall be provided at the time of preadmission or admission to each person who seeks services in the hospital.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

JHBMC submitted a copy of its charity care policy and it complies with the requirements of this standard with respect to determinations of probable eligibility, public notice, and individual notice. For example, the policy is published annually in the Baltimore Sun and the

applicant states that it is posted in the admissions and ED "and patient billing and financial assistance information is provided..in the Patient Handbook." However, while not required, Commission staff could not find JHBMC's charity care policy on its website and recommends that JHBMC post its charity care policy on its patient and visitors page to raise awareness by those patients who may have a need for assistance.

JHBMC provided a copy of the reported charity care table from the FY2010 *Community Benefit Report* showed JHBMC to be in the top quartile of Maryland hospitals ranked by level of charity care provided; it ranked 11th among the state's 46 general hospitals, providing more than $21 million in charity care or 4.3% of its total operating expenses.

The applicant complies with this standard.

(3) Quality of Care

An acute care hospital shall provide high quality care.

(a) Each hospital shall document that it is:

(i) Licensed, in good standing, by the Maryland Department of Health and Mental Hygiene;

(ii) Accredited by the Joint Commission; and

(iii) In compliance with the conditions of participation of the Medicare and Medicaid programs.

(b) A hospital with a measure value for a Quality Measure included in the most recent update of the Maryland Hospital Performance Evaluation Guide that falls within the bottom quartile of all hospitals' reported performance measured for that Quality Measure and also falls below a 90% level of compliance with the Quality Measure, shall document each action it is taking to improve performance for that Quality Measure.

JHBMC documented its current licensure (expiration February 7, 2013) and accreditation status. It is accredited by the Joint Commission (November 7, 2009 for 39 months). JHBMC is in compliance with the conditions of participation of the Medicare and Medicaid programs.

Of the quality measures published by MHCC on its website, JHBMC's performance in 2010 fell in the bottom quartile and was less than 90% for the four measures shown below:

Table 7: JHBMC Bottom Quartile Performance on Quality Measures - 2010

Quality Measure	JHBMC Compliance Level (%*)	State Average Compliance Level (%)	JHBMC Rank	Number of Hospitals Reporting for this Measure (n)
Heart Failure (CHF)				
1. Discharge instructions	75	87	40	45
Pneumonia				
1. Antibiotics within 6 hours	89	95	42	45
2. Influenza vaccination status	80	90	38	44
3. Pneumococcal Vaccination	82	93	41	45

Source: Maryland Hospital Performance Guide, MHCC website and Exhibit 7 of CON application.

JHBMC states that an electronic patient discharge instruction form was implemented which includes an import of the patient home medications from the Electronic Medical Record (EMR), allowing them to be copied by physicians and nurse practitioners into the discharge summary, making the two lists identical. In October, the discharge instructions and summary were to be electronically integrated while ongoing auditing continues. The applicant did provide data that shows compliance with heart failure discharge instructions rising to 97% in June 2011, after some fluctuation in previous months.

Relative to the vaccines, a nurse driven protocol was implemented to facilitate vaccination. Ongoing follow-up audits were implemented with feedback to Clinical Specialists who retrain nurses who didn't complete the protocol correctly. Moreover, nurses who fail to correctly implement the protocol receive a communication from the Department of Quality. JHBMC reports dramatic improvement as a result of these efforts with pneumococcal and influenza vaccination compliance growing to 100% and more than 97%, respectively, in March 2011, although pneumococcal fell to 87% in June 2011.

Ongoing concurrent review was implemented by the Department of Quality of patients presenting in the ED with pneumonia, which has helped to identify and correct documentation of diagnostic uncertainty in this patient population. Every time there is a failure in this core measure indictor, the Department of Quality provides communication to emergency department providers. Again, JHBMC reports excellent compliance. Data for the first six months of 2011 show significant improvement in compliance relative to the delivery of antibiotics for pneumonia within six hours, achieving 100% in June 2011.

Based on these efforts, JHBMC has complied with this standard.

COMAR 10.24.10.04B-Project Review Standards

(1) <u>Geographic Accessibility</u> A new acute care general hospital or an acute care general hospital being replaced on a new site shall be located to optimize accessibility in terms of travel time for its likely service area population. Optimal travel time for general medical/surgical, intensive/critical care and pediatric services shall be within 30 minutes under normal driving conditions for 90 percent of the population in its likely service area.

This standard is not applicable to this project. No new or replacement hospital is proposed.

(2) <u>Identification of Bed Need and Addition of Beds</u>

Only medical/surgical/gynecological/addictions ("MSGA") beds and pediatric beds identified as needed and/or currently licensed shall be developed at acute care general hospitals.

(a) Minimum and maximum need for MSGA and pediatric beds are determined using the need projection methodologies in Regulation .05 of this Chapter.

(b) Projected need for trauma unit, intensive care unit, critical care unit, progressive care unit, and care for AIDS patients is included in the MSGA need projection.

(c) Additional MSGA or pediatric beds may be developed or put into operation only if:

(i) The proposed additional beds will not cause the total bed capacity of the hospital to exceed the most recent annual calculation of licensed bed capacity for the hospital made pursuant to Health-General §19-307.2; or

(ii) The proposed additional beds do not exceed the minimum jurisdictional bed need projection adopted by the Commission and calculated using the bed need projection methodology in Regulation .05 of this Chapter; or

(iii) The proposed additional beds exceed the minimum jurisdictional bed need projection but do not exceed the maximum jurisdictional bed need projection adopted by the Commission and calculated using the bed need projection methodology in Regulation .05 of this Chapter and the applicant can demonstrate need at the applicant hospital for bed capacity that exceeds the minimum jurisdictional bed need projection; or

(iv) The number of proposed additional MSGA or pediatric beds may be derived through application of the projection methodology, assumptions, and targets contained in Regulation .05 of this Chapter, as applied to the service area of the hospital.

This standard does not apply to this project. No additional MSGA or pediatric beds or change in licensed bed inventory is being requested by the applicant.

(3) <u>Minimum Average Daily Census for Establishment of a Pediatric Unit</u>

An acute care general hospital may establish a new pediatric service only if the projected average daily census of pediatric patients to be served by the hospital is at least five patients, unless:

(a) The hospital is located more than 30 minutes travel time under normal driving conditions from a hospital with a pediatric unit; or

(b) The hospital is the sole provider of acute care general hospital services in its jurisdiction.

This standard does not apply to this project. A new pediatric service is not being established.

(4) <u>Adverse Impact</u>

A capital project undertaken by a hospital shall not have an unwarranted adverse impact on hospital charges, availability of services, or access to services. The Commission will grant a Certificate of Need only if the hospital documents the following:

(a) If the hospital is seeking an increase in rates from the Health Services Cost Review Commission to account for the increase in capital costs associated with the proposed project and the hospital has a fully-adjusted Charge Per Case that exceeds the fully adjusted average Charge Per Case for its peer group, the hospital must document that its Debt to Capitalization ratio is below the average ratio for its peer group. In addition, if the project involves replacement of physical plant assets, the hospital must document that the age of the physical plant assets being replaced exceed the Average Age of Plant for its peer group or otherwise demonstrate why the physical plant assets require replacement in order to achieve the primary objectives of the project; and

(b) If the project reduces the potential availability or accessibility of a facility or service

by eliminating, downsizing, or otherwise modifying a facility or service, the applicant shall document that each proposed change will not inappropriately diminish, for the population in the primary service area, the availability or accessibility to care, including access for the indigent and/or uninsured.

With respect to paragraph (a), JHBMC is not requesting an HSCRC rate adjustment to cover the capital costs related to this project, but reserves the right to include those capital costs related to hospital services in future rate proceedings with the HSCRC.

As for the requirements found in paragraph (b), JHBMC is not proposing to eliminate or downsize any facility or service. Rather, it is proposing to expand its oncology services and the physical facility for oncology service delivery. This project will not alter geographic access or access to services by the indigent or uninsured for the oncology services currently provided by JHBMC. It will marginally improve geographic access to radiation oncology services by creating a new site for this service but the JHBMC site is not distant from existing sites from this service.

(5) Cost-Effectiveness

A proposed hospital capital project should represent the most cost effective approach to meeting the needs that the project seeks to address.

(a) To demonstrate cost effectiveness, an applicant shall identify each primary objective of its proposed project and shall identify at least two alternative approaches that it considered for achieving these primary objectives. For each approach, the hospital must:

(i) To the extent possible, quantify the level of effectiveness of each alternative in achieving each primary objective;

(ii) Detail the capital and operational cost estimates and projections developed by the hospital for each alternative; and

(iii) Explain the basis for choosing the proposed project and rejecting alternative approaches to achieving the project's objectives.

(b) An applicant proposing a project involving limited objectives, including, but not limited to, the introduction of a new single service, the expansion of capacity for a single service, or a project limited to renovation of an existing facility for purposes of modernization, may address the cost-effectiveness of the project without undertaking the analysis outlined in (a) above, by demonstrating that there is only one practical approach to achieving the project's objectives.

(c) An applicant proposing establishment of a new hospital or relocation of an existing hospital to a new site that is not within a Priority Funding Area as defined under Title 5, Subtitle 7B of the State Finance and Procurement Article of the Annotated Code of Maryland shall demonstrate:

(i) That it has considered, at a minimum, the two alternative project sites located within a Priority Funding Area that provide the most optimal geographic accessibility to the population in its likely service area, as defined in Project Review Standard (1);

(ii) That it has quantified, to the extent possible, the level of effectiveness, in terms of achieving primary project objectives, of implementing the proposed project at each alternative project site and at the proposed project site;

(iii) That it has detailed the capital and operational costs associated with implementing the project at each alternative project site and at the proposed project site, with a full accounting of the cost associated with transportation system and other public utility infrastructure costs; and
(iv) That the proposed project site is superior, in terms of cost-effectiveness, to the alternative project sites located within a Priority Funding Area.

Only paragraph (a) applies to this CON application as it is neither limited in scope nor intended to result in the establishment of a new hospital or relocation of an existing hospital to a new site.

JHBMC identified the primary objectives of this project to be:

- Provide JHBMC oncology/hematology patients with comprehensive cancer care in a fully integrated clinical and academic cancer center including on-site radiation therapy.
- Expand hematology and medical oncology consult/exam and infusion stations.
- Establish a Lung Cancer center of excellence at the JHBMC campus.

Two alternative approaches, discussed below, were considered for achieving these primary objectives.

Alternative #1) Renovation and expansion in the Burton Pavilion.

This alternative would have taken the entire floor of the Burton Pavilion ("BP") where the oncology/hematology program is currently located and create additional space by filling in the courtyard between the two existing wings for a total of 15,500 GSF, which would result in tight rooms and no room for additional space. By comparison, the proposed BMO space is able to accommodate 26,000 SF on a single floor with adjacent space for future expansion. Moreover, the existing child care program on the current floor would have to be relocated.

Also, the existing BP location doesn't provide good access to diagnostic imaging, inpatient facilities, and emergency department. There is a tunnel but it is reported by the applicant as being inconvenient and unattractive for transporting patients and there is very limited nearby parking available at BP for the larger numbers of outpatients expected with expanded exam rooms and radiation oncology. BP was designed originally for comprehensive and chronic care which has been determined to be the best use of the building.

Commission staff notes that the space available through this alternative could be a more viable alternative for consolidation and expansion of cancer services without introduction of radiation therapy. Moreover, without radiation therapy, the demand for parking would be reduced. The applicant did not provide information regarding the number of current or expected emergency transports from its outpatient center in order to evaluate the need for location closer to the emergency department.

Alternative #2) Locate on the first floor of the 301 Building.

The first level of the 301 Building has usable space of 18,500 SF consisting of four pods of 4-5,000 SF each which included the building lobby and main circulation/fire exit corridors. This is not deemed to be adequate for the Cancer Center which requires 22,000 SF of contiguous space, as programmed. Moreover, the 301 Building lacks the HVAC, emergency power, and medical gases required to support an Oncology Clinic and would be costly to add.

Another challenge is the distance of the 301 Building from the main hospital, particularly the Blood Bank and Core Lab, which are continuously in communication with Hematology and Oncology Infusion. Also, while the Oncology Clinic program includes a full Oncology Pharmacy, patients require take home medication that would be acquired from the Outpatient Pharmacy, which is located on the Main Level of the BMO. Finally, according to the applicant, service for inpatients would be compromised because of this building's disconnect from the main hospital. The 301 Building was designed to accommodate low-acuity, outpatient services, with a lack of hospital grade infrastructure. It is not considered to be a good option for the Cancer Center, which will require specialized equipment and extensive service utilities.

The hospital has met the requirements of this standard by providing the required information and analysis of alternatives to the proposed project. It has demonstrated that the proposed capital project represents the most cost effective approach to meeting the needs that the project seeks to address.

(6) Burden of Proof Regarding Need

A hospital project shall be approved only if there is demonstrable need. The burden of demonstrating need for a service not covered by Regulation .05 of this Chapter or by another chapter of the State Health Plan, including a service for which need is not separately projected, rests with the applicant.

See discussion of project need under COMAR 10.24.01.08G(3)(b). Need.

(7) Construction Cost of Hospital Space

The proposed cost of a hospital construction project shall be reasonable and consistent with current industry cost experience in Maryland. The projected cost per square foot of a hospital construction project or renovation project shall be compared to the benchmark cost of good quality Class A hospital construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

This standard requires a comparison of the project's estimated new construction and renovation cost with an index cost derived from Marshall Valuation Service ("MVS") guidelines for new construction. Staff evaluated the project costs, as they would be appropriately adjusted for comparison with an MVS benchmark cost and this evaluation is summarized in the following table.

Table 8: Construction Cost Analysis
Johns Hopkins Bayview Medical Center

	New Construction	Renovation	Total
Building	$8,468,544	$3,111,004	$11,579,548
Normal Site Preparation	945,924	$0.00	945,924
Architect/Engineering Fees	877,500	356,738	1,234,238
Permits	46,965	15,633	62,598
Capitalized Construction Interest	764,417	257,652	1,022,069
Total Project Costs	$11,103,350	$3,741,027	$14,844,377
Total Adjustments	$2,950,455	$519,389	$3,469,844
Net Project Costs	$8,152,895	$3,221,638	$11,374,533
Square Footage	18,030	10,530	28,560
Cost Per Square Ft.	$452.18	$305.95	
Adj. MVS Cost/Square Foot	$425.08	$445.99	
Over(Under)	$27.11	-$140.04	
Excess (Under)	$488,768	-$1,474,630	-$985,862

Source: Submission dated 10/26/2011, Project Budget; MVS Analysis (DI #15)

Staff adjusted for extraordinary costs recognized as valid adjustments under the MVS guidelines. (e.g., non-normal landscaping and canopy costs). In addition, staff also adjusted for departmental differentials. New construction and renovation are both scheduled for the first floor level.

The standard requires that any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of project construction costs that exceeds the MVS benchmark and those portions of the contingency allowance, inflation allowance and capital construction interest that are based on the excess construction. In this case, while the new construction component has an adjusted cost estimate that exceeds the MVS benchmark, on a combined basis, the new construction and renovation components do not, in the aggregate, result in construction/renovation costs that are excessive.

(8) Construction Cost of Non-Hospital Space

The proposed construction costs of non-hospital space shall be reasonable and in line with current industry cost experience. The projected cost per square foot of non-hospital space shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide for the appropriate structure. If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the non-hospital space shall not include the amount of the projected construction cost that exceeds the Marshall Valuation Service® benchmark and those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost. In

general, rate increases authorized for hospitals should not recognize the costs associated with construction of non-hospital space.

This standard is not applicable to this project. Construction of non-hospital space is not proposed by JHBMC.

(9) Inpatient Nursing Unit Space

Space built or renovated for inpatient nursing units that exceeds reasonable space standards per bed for the type of unit being developed shall not be recognized in a rate adjustment. If the Inpatient Unit Program Space per bed of a new or modified inpatient nursing unit exceeds 500 square feet per bed, any rate increase proposed by the hospital related to the capital cost of the project shall not include the amount of the projected construction cost for the space that exceeds the per bed square footage limitation in this standard or those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess space.

Not applicable to this project.

(10) Rate Reduction Agreement

A high-charge hospital will not be granted a Certificate of Need to establish a new acute care service, or to construct, renovate, upgrade, expand, or modernize acute care facilities, including support and ancillary facilities, unless it has first agreed to enter into a rate reduction agreement with the Health Services Cost Review Commission, or the Health Services Cost Review Commission has determined that a rate reduction agreement is not necessary.

This standard is not applicable. JHBMC is not a high-charge hospital. The HSCRC 2010 Reasonableness of Charges Comparison report found that JHBMC's charge per case was approximately 1% below (0.94%) the average charge per case for its Peer Group (Peer Group 4 – Urban Hospitals).

(11) Efficiency

A hospital shall be designed to operate efficiently. Hospitals proposing to replace or expand diagnostic or treatment facilities and services shall:

(a) Provide an analysis of each change in operational efficiency projected for each diagnostic or treatment facility and service being replaced or expanded, and document the manner in which the planning and design of the project took efficiency improvements into account; and

(b) Demonstrate that the proposed project will improve operational efficiency when the proposed replacement or expanded diagnostic or treatment facilities and services are projected to experience increases in the volume of services delivered; or

(c) Demonstrate why improvements in operational efficiency cannot be achieved.

JHBMC states that the project encompasses for following efficiencies:

- Collocating radiation, medical oncology/hematology and medical infusion allows the sharing of staffing and space, as volumes flex for each service;

- Patient outcomes and safety will be enhanced from the use of common protocols and clinical guidelines;

- Fully integrating JHBMC's proposed radiation oncology program with the John Hopkins Hospital and Greenspring radiation therapy facilities will allow the sharing of treatment protocols, safety standards, and operating procedures across campuses driving efficiency of operations for physics, dosimetry, and therapy staff;

- The same equipment and information technology platform will allow for collaborative planning and data sharing, providing back-up for equipment maintenance;

- The peer review process can be integrated across campuses to enhance safety and quality assurance review by all faculty;

- Space for multidisciplinary clinics allows rapid diagnosis and development of treatment plans across disciplines for newly diagnosed cancer patients, allowing patients to be treated more efficiently and avoids duplication of diagnostic testing; and

- Improved patient convenience will be realized with the co-location of needed services.

The applicant has demonstrated that the project will achieve operational efficiencies. The project complies with this standard.

(12) <u>Patient Safety</u>

The design of a hospital project shall take patient safety into consideration and shall include design features that enhance and improve patient safety. A hospital proposing to replace or expand its physical plant shall provide an analysis of patient safety features included for each facility or service being replaced or expanded, and document the manner in which the planning and design of the project took patient safety into account.

The applicant outlined design and operational characteristics incorporated in its proposed project that it believes will have a positive impact on patient safety, summarized as follows:

- Medical oncology patients will no longer need to be transported by ambulance if they need emergency care due to the ability to internally transfer patients, as well as being within access of the hospital code team;

- Nurses in the chemo-infusion area will allow staff to observe all patients under treatment at all times. The centrally located nursing station will allow staff to cover chemotherapy checks for one another and the pharmacist will be co-located in the infusion area;

- Space will be available in the infusion area to isolate a patient;

- Radiation oncology equipment will have state of the art CT and ultrasound image guidance systems to enhance tumor targeting;

- The integration of a digitally integrated linear accelerator and information control systems allows dose delivery to the smallest dose necessary and hard stop safety features;

- Standardized systems with a single integrated team will help manage quality assurance, safety protocols, and State regulatory requirements;

- Academic research in radiation oncology patient safety will be extended to and integrated with research and operations;

- A single comprehensive center will minimize care management, data transfer, and clinical "hand offs" across multiple campuses and promote integrated nursing care; and

- Integrated multi-disciplinary consultation and evaluation will ensure cancer patients receive the most effective and safest individualized care plan.

The applicant has demonstrated that design of its project took patient safety into consideration and that it includes features that enhance and improve patient safety, consistent with this standard.

(13) <u>Financial Feasibility</u>

A hospital capital project shall be financially feasible and shall not jeopardize the long-term financial viability of the hospital.

(a) Financial projections filed as part of a hospital Certificate of Need application must be accompanied by a statement containing each assumption used to develop the projections.

The applicant states that financial projections were developed as part of a detailed financial projection for the entire acute hospital, utilizing a long-range financial planning model developed by KPMG. The JHBMC/KPMG planning model uses projected inpatient discharges and case mix index, outpatient volumes by HSCRC rate center, and current JHBMC HSCRC rates to project revenue. Projected equivalent inpatient admissions (EIPAs) and current expense per EIPA are used to project operating expenses. Capital and debt expenses are projected separately based on assumed capital expenditures and debt financings. FY 2013 - 2019 financial projection assumptions can be summarized as follows:

1. Revenues:
   a. Gross revenue based on current estimated FY 2012 HSCRC rates applied to projected volumes.
   b. Inflation:
      • HSCRC update factor 2.00% FY13-15

• HSCRC update factor 2.50% FY16-18
• HSCRC update factor 2.75% FY19
• Other operating revenues 3.00%

c. Current HSCRC 15% reductions for fixed costs on incremental inpatient and outpatient revenue continues.

d. Current FY 2012 budgeted revenue deductions for regulatory allowances, bad debt and charity care percentages applied to gross revenue.

e. No change in other operating revenue, except 3.00% inflation on the updated Table 3 and no inflation on original Table 3 submitted.

2. Expenses

a. 3.00% Inflation on the updated Table 3 and no inflation on original Table 3 submitted.

b. Expense is 70% variable with volume and Case Mix Index changes.

c. Bond issuance assumes a 30 year fixed rate of 5.45%.

d. Debt financing costs estimated to be 0.6% of bond size.

(b) Each applicant must document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the service area population of the hospital or State Health Plan need projections, if relevant;

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant hospital or, if a new hospital, the recent experience of other similar hospitals;

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant hospital, or, if a new hospital, the recent experience of other similar hospitals; and

(iv) The hospital will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years or less of initiating operations with the exception that a hospital may receive a Certificate of Need for a project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project when the hospital can demonstrate that overall hospital financial performance will be positive and that the services will benefit the hospital's primary service area population.

With respect to subsection (i), the applicant states that patient oncology volume projections were based on historic growth in JHBMC Tumor Registry cases, excluding prostate cancer. From 2005 to 2009 these cases increased at an annual rate of 6.7% at JHBMC. The projections for this application assume an annual increase in tumor cases of 4.0%, holding prostate cancer volume flat. Projected radiation therapy treatments per year were calculated based on annual tumor cases, the percent of these cases receiving radiation therapy, and the number of treatments per patient. Chemotherapy visits are projected to grow 3.0% per year based on Sg2 modeling forecasts, and are consistent with the 4.0% tumor growth projection. Medical and Surgical inpatient admissions and outpatient visits are projected to grow at an annual rate of

5.0%, which is higher than tumor cases due to longer patient survival.

However MHCC staff notes that JHBMC projects its number of radiation therapy in the first year of operations (FY2015) to be 162 which would represent a 19% increase over the number of its radiation therapy patients who currently stay in the area to receive radiation therapy. It also projects the percentage of its tumor cases receiving radiation oncology to grow from 18 to 20 percent and its treatments per patient to be 29 (a 2004 statistic). These appear to be somewhat ambitious in light of increased research into alternatives to and the optimization of radiation therapy treatments based on clinical efficacy, as well as the declining number of cancer cases in JHBMC's service area.

With respect to subsection (ii), JHBMC specified that revenue is projected based on the current estimated FY 2012 HSCRC rates with current adjustments, discounts, bad debt and charity care. Changes in Case mix Index due to projected changes for inpatient service volume mixes are also taken into account.

With respect to subsection (iii), expenses are projected based on the current FY 2012 budgeted expenses, adjusted for volume changes and the incremental staffing related to this project shown in Table 5.

With respect to subsection (iv), JHBMC is projecting the project will generate positive net income beginning in the first year that it comes on-line.

The applicant has demonstrated the financial feasibility of the project, under the terms of this standard. A preliminary positive opinion with respect to financial feasibility has been communicated by HSCRC staff. Its written opinion was not available at the time of posting of this report.

(14) <u>Emergency Department Treatment Capacity and Space</u>

(a) An applicant proposing a new or expanded emergency department shall classify service as low range or high range based on the parameters in the most recent edition of Emergency Department Design: A Practical Guide to Planning for the Future from the American College of Emergency Physicians. The number of emergency department treatment spaces and the departmental space proposed by the applicant shall be consistent with the range set forth in the most recent edition of the American College of Emergency Physicians Emergency Department Design: A Practical Guide to Planning for the Future, given the classification of the emergency department as low or high range and the projected emergency department visit volume.

(b) In developing projections of emergency department visit volume, the applicant shall consider, at a minimum:

(i) The existing and projected primary service areas of the hospital, historic trends in emergency department utilization at the hospital, and the number of hospital emergency department service providers in the applicant hospital's primary service areas;

(ii) The number of uninsured, underinsured, indigent, and otherwise underserved

patients in the applicant's primary service area and the impact of these patient groups on emergency department use;
(iii) Any demographic or health service utilization data and/or analyses that support the need for the proposed project;
(iv) The impact of efforts the applicant has made or will make to divert non-emergency cases from its emergency department to more appropriate primary care or urgent care settings; and
(v) Any other relevant information on the unmet need for emergency department or urgent care services in the service area.

(15) <u>Emergency Department Expansion</u>

A hospital proposing expansion of emergency department treatment capacity shall demonstrate that it has made appropriate efforts, consistent with federal and state law, to maximize effective use of existing capacity for emergent medical needs and has appropriately integrated emergency department planning with planning for bed capacity, and diagnostic and treatment service capacity. At a minimum:

(a) The applicant hospital must demonstrate that, in cooperation with its medical staff, it has attempted to reduce use of its emergency department for non-emergency medical care. This demonstration shall, at a minimum, address the feasibility of reducing or redirecting patients with non-emergent illnesses, injuries, and conditions, to lower cost alternative facilities or programs;
(b) The applicant hospital must demonstrate that it has effectively managed its existing emergency department treatment capacity to maximize use; and
(c) The applicant hospital must demonstrate that it has considered the need for bed and other facility and system capacity that will be affected by greater volumes of emergency department patients.

This project does not involve ED services at JHBMC; therefore, these standards are not applicable.

(16) <u>Shell Space</u>

Unfinished hospital space for which there is no immediate need or use, known as "shell space," shall not be built unless the applicant can demonstrate that construction of the shell space is cost effective. If the proposed shell space is not supporting finished building space being constructed above the shell space, the applicant shall provide an analysis demonstrating that constructing the space in the proposed time frame has a positive net present value that considers the most likely use identified by the hospital for the unfinished space and the time frame projected for finishing the space. The applicant shall demonstrate that the hospital is likely to need the space for the most likely identified use in the projected time frame. Shell space being constructed on lower floors of a building addition that supports finished building space on upper floors does not require a net present value analysis. Applicants shall provide information on the cost, the most likely uses, and the likely time frame for using such shell space. The cost of shell space included in an approved project and those portions of the contingency allowance, inflation allowance, and capitalized construction

interest expenditure that are based on the construction cost of the shell space will be excluded from consideration in any rate adjustment by the Health Service Cost Review Commission.

This standard is not applicable. The project does not propose construction of shell space.

B. Need

COMAR 10.24.01.08G(3)(b) Need.
The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

There is no applicable need analysis in the State Health Plan for radiation therapy or the establishment of a cancer care center, because these services are not categorically regulated under Maryland's CON program. (As previously noted, JHBMC could undertake this project without CON approval, if it were willing to forego the opportunity to, in the future, seek substantive rate adjustments to help pay for the project.) It is the applicant's responsibility to demonstrate an unmet need(s) of the population to be served and that the proposed project meets those needs. According to the applicant, "(T)he Oncology expansion plan at JHBMC is not just to grow radiation oncology linear accelerator capacity; rather the strategy is to provide JHBMC oncology patients with comprehensive cancer care in a fully integrated clinical and academic cancer center." The stated goals are to:

- expand the Sidney Kimmel Comprehensive Cancer Center (SKCCC) to the JHBMC Campus;

- increase access to cancer patients seeking care;
- innovate delivery of multi-disciplinary care to cancer patients seeking oncology services;

- provide enhanced comprehensive clinical trial access under one roof to the cancer patients seeking care at JHBMC; and

- develop a lung cancer center of excellence for JHBMC which will focus on developing innovative laboratory-based protocols that will be translated into clinical treatment applications for lung cancer patients.

As provided by the applicant in the table below and confirmed by Commission staff, the number of cancer cases has increased slightly from 2000 to 2007 in Central Maryland but declined in JHBMC's primary service area (Baltimore City and County). Moreover, the age-adjusted cancer incidence rate has declined because the population is growing faster than the reported number of new cancer cases.

Table 9: New Cancer Cases, 2000 & 2007
Maryland and Selected Jurisdictions

Jurisdiction	Number New Cancer Cases		Age-Adjusted Incidence Rate	
	2000	2007	2000	2007
Maryland	24,551	26,377	486.0	455.3
Anne Arundel	2,245	2,488	504.9	486.0
Baltimore City	3,321	2,975	505.8	459.6
Baltimore County	4,307	4,155	514.0	458.5
Carroll	711	825	505.3	473.7
Harford	995	1,244	510.0	515.6
Howard	880	1,128	454.6	445.1
Central Maryland	12,459	12,815		

Source: Maryland Cancer Registry, 2000 and 2007.

According to the Maryland Department of Health and Mental Hygiene's 2010 Revised Cancer Report, State mortality rates for all cancer sites decreased from 1998 to 2007 with blacks having higher mortality rates than whites, although the average yearly decline for blacks is greater than the decline for whites. Nevertheless, in 2007, the age-adjusted mortality rate due to cancer was 180.4 per 100,000 population in Maryland compared to 221.5 in Baltimore City and 178.4 in Baltimore County. Declines in age-adjusted mortality rates due to cancer may reflect better screening and early treatment, perhaps reduced even further in the future by increased insurance coverage and the requirement that screenings not be subject to cost sharing as specified by national health reform. Increased coverage may increase demand for early treatment services for cancer care. The applicant cites that Sg2 (a consulting firm) forecasts a national increase in outpatient encounters for cancer services by more than 38% by 2021.

While the total number of cancer cases has declined in JHBMC's service area and at JHBMC, the actual number has increased if you disregard the significant decline in prostate cases. As illustrated on page 45 of its application, JHBMC is forecasting that its prostate cases will remain at 2009 levels through 2016 while some other types of cancer will increase significantly during that period, for a forecasted overall annual growth rate from 2010 to 2016 of 4%. Based on cancer incidence trends, it would appear that this growth can only be sustained through capture of additional market share by JHBMC.

JHBMC explains that its "forecast is considered to be conservative given the recent program developments and investments made at JHBMC. In late 2009 with the completion of the operating room expansion project, two new neurosurgical operating rooms were created with intraoperative CT and image-guided surgery systems. This intraoperative CT capability has a positive effect on patient outcomes by improving safety, decreasing infections and lowering the risks of complications. Brain & central nervous system tumor cases increased from 44 in 2008, to 75 in 2009 with the expansion of this service."

In 2010, JHBMC purchased robotic surgery equipment to enhance its minimally invasive surgical services. For prostate surgery, the use of robotic surgery has become a community standard of care and JHBMC expects that, with this equipment and additional urology faculty. further declines in the volume of new prostate cases will not occur. "In 2012, JHBMC will open a new breast center as part of the Johns Hopkins Breast Cancer program. With the opening of the Breast Center, the mammography equipment will be upgraded to digital capabilities and a multidisciplinary center will be created for radiology, surgery and other specialists. In 2009, the annual breast tumor cases were only 51 at JHBMC compared to most hospitals in the 200-300 range."

Need For Radiation Oncology:

According to JHBMC, "it is estimated that 60% of all newly diagnosed cancer patients will receive radiation therapy and radiation therapy is often used in conjunction with other cancer interventions, including surgery and chemotherapy. The coordination and efficient flow of patient information between specialists and sites of care are important to patient safety and outcomes. Delays in the start of radiation therapy, or interruptions in treatment schedules, can compromise outcomes. In CY2009, 21 % of the 756 JHBMC tumor patients received radiation therapy during their first course of treatment. Cancer sites with significant volumes having a high utilization - radiation therapy as part of the first course of therapy included respiratory (lung & bronchus), breast, head & neck and brain." JHBMC reports only 242 of these cases in 2009.

The applicant identifies seven hospitals in Central Maryland with a smaller number of new cancer patients that have on-site radiation oncology. Based on CY2009 tumor registry data, there were 154 patient referred for first course radiation therapy treatment from JHBMC. The majority of JHBMC patients (75%) are referred to either The John Hopkins Hospital (JHH) or Greenspring Station, a Hopkins System outpatient center, for treatment, 11% are referred to other Central Maryland facilities and 12% are referred outside of Central Maryland. The applicant notes that patients referred outside the area prefer to receive treatment close to home.

As illustrated by the following table provided by the applicant, JHH treated an average of 126.5 patients per day on one of its five linear accelerators (average of approximately 25 per day or 2.5 per hour based on a 10 hour treatment day) and 23.7 patients per day at its Green Spring Station outpatient center on its single linear accelerator. The applicant explains that this 10 hour treatment day (7 a.m. – 5 p.m.) allows for 30 minutes use prior to 7 a.m. for quality assurance use and the need to perform treatment and physics quality assurance on the machines for one to two hours following the end of treatments. The conclusion is that there is some available capacity at Green Spring Station but not at JHH, but, of course, the patients currently being referred by JHBMC (approximately 115 patients annually) would increase that capacity should JHBMC open its own radiation therapy facility.

Table 10: Linear Accelerator Use, FY2011

The Johns Hopkins Hospital and Greenspring Station FY11 Linear Accelerator Utilization, Per Treatment Day

Calculations		a	b	c	d	e=a-d	f=e/b	g=c+f	h	i=h/g
Machine name	Number of Linear Accelerators	Minutes per 10 Hour Treatment Day	FY11 Actual Avg Treatment Time (Minutes)	FY11 Actual New Starts (Patients)	Projected New Start Utilization (Minutes)	Projected Capacity for Treatment (Minutes)	Projected Treatment Capacity (patients)	Projected Daily Linac Capacity (Patients)	FY11 Actual Avg Patients Treated per Day	Linac Utilization
Green Spring Station	1	600	19	1	60	540	28	29	23.7	82%
JHH	5	3000	25	5.8	348	2652	106	112	126.5	113%
Total JHH & GSS	**6**	**3600**	**24**	**6.8**	**408**	**3192**	**133**	**140**	**150.2**	**107%**

Source: JHM Mosaiq Schedule, Treatment, and Billed Data

No information was provided regarding the available capacity of other area radiation therapy providers to determine the community need for additional radiation therapy capacity in Central Maryland or its primary service area. Of course, the approximately 17 patients referred to other area radiation therapy facilities would create additional capacity, although minimal, in the community should JHBMC change its referrals to them with introduction of a linear accelerator.

As illustrated in the following table JHBMC projects its number of radiation therapy patients in the first year of operations (FY2015) to be 162 which would represent a 19% increase over the number of its radiation therapy patients who currently stay in the area to receive radiation therapy. It also projects the percentage of its tumor cases receiving radiation oncology to grow from 18 to 20 percent and its treatments per patient to be 29 (based on a 2004 statistic). These may be ambitious assumptions in light of increased research into alternatives to and the optimization of radiation therapy treatments based on clinical efficacy, as well as the declining number of cancer cases in JHBMC's service area.

Table 11: Projected Linear Accelerator Use
JHBMC - FY2015-2019

Johns Hopkins Bayview Medical Center
Forecast Radiation Therapy Treatments

Fiscal Year	Annual Tumor Cases*	% Radiation Oncology Referrals	# Radiation Oncology Patients	Treatments Per Patient**	Annual Treatments	Average Treatments Per Day
FY 2015	919	18%	162	29	4697	18
FY 2016	956	18%	172	29	4995	20
FY 2017	994	19%	185	29	5370	21
FY 2018	1033	19%	199	29	5778	23
FY 2019	1074	20%	215	29	6242	25

* Annual Tumor Cases based on CY Registry, CY14=FY15, CY15=FY16, etc

** American Society for Radiation Oncology estimated average treatments per patient.

Commission staff concludes that the applicant has not made a compelling case that there is a fundamental population need for the establishment of an additional radiation therapy service site in the JHBMC service area, in terms of significant deficiencies in the ready availability and

accessibility of these services in the region. Clearly, the introduction of this service provides an improvement in continuity of oncology services for those cancer patients using the established services of JHBMC.

Demand for Chemotherapy Infusion:

JHBMC explains that the growth in expected oncology visits will also impact chemotherapy demand, creating additional demand. The applicant cites Sg2's forecast of a 33% projected increase in chemotherapy outpatient visits from 2009-2019, compared to a 17% population-based increase. Reasons given for this include:

- Heightened patient risks for recurrence or secondary malignancy due to increased survivorship;
- Expanding applications for existing chemotherapy drugs;
- Increasing number of multimodality treatment protocols (e.g. radiation therapy plus chemotherapy); and
- Growing use of molecular diagnostic testing to identify appropriate chemotherapeutic candidates.

JHBMC estimates that half of all new cancer patients will utilize chemotherapy. The following table shows that JHBMC performed approximately 4,500 infusions in its 11 medical oncology/hematology infusion chairs and almost 2,100 in its 8 medical infusion chairs. "Using the mean AMC benchmark of 409 infusions per chair (based on The Advisory Board 2008 Oncology Roundtable Benchmark Survey), the current utilization of the 19 chair combined capacity is 85% utilization. Upon project completion, the new infusion center will have 21 infusion spaces, 18 infusion bays and 3 private infusion rooms. Using the Sg2 forecast chemotherapy average growth rate of 3% per year until 2019, total chemotherapy visits are projected to be 5,717 in FY19. The medical infusion clinic is assumed to remain stable, with no growth projected through FY2019."

Table 12: Historic (2011) & Projected (2015-2019) Cancer-Related Services
JHBMC - FY2015-2019

Johns Hopkins Bayview Medical Center Forecast Combined Chemotherapy and Medical Infusion							
Fiscal Year	FY 2011	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	Annual Growth
Annual Chemo Infusions	4513	5,079	5,232	5,389	5,550	5,717	3.0%
Annual Medical Infusions	2094	2,100	2,100	2,100	2,100	2,100	0.0%
Combined Infusions	6607	7,179	7,332	7,489	7,650	7,817	2.1%
Total Infusion Chairs	19	21	21	21	21	21	NA
Annual Infusion Capacity	7,771	8,589	8,589	8,589	8,589	8,589	NA
% Chair Utilization	85%	84%	85%	87%	89%	91%	NA

Notes: FY11 capacity 11 chairs chemo and 8 chairs medical infusion.
Infusion capacity based on 409 annual visits per chair.

Should its projections be achieved, JHBMC would provide an average of 372 infusions per chair annually, or less than 1.5 infusions per chair each weekday.

As with radiation therapy, staff concludes that the applicant has not definitively shown a fundamental population need for this aspect of the project in the sense that the population's access to infusion therapy will be substantively jeopardized without implementation of this project. Certainly, growth in demand appears likely and the consolidation of the currently separated infusion facilities at JHBMC can provide substantial operational efficiencies.

Conclusions

It is difficult to conclude that this project is necessary for the population of JHBMC's service area to obtain adequate and timely oncology services. However, because MHCC does not categorically regulate any of the clinical services affected by this project, the Commission has not articulated specific policies, criteria, or standards that provide guidance on how population need for these services is defined or should be evaluated. Standardized approaches to collecting and assessing data for these services useful in the regulation of their supply have not been developed. This places the applicant and the Commission at a disadvantage in justifying the project on the basis of population need or passing judgment on this criteria.

It is reasonable to conclude that this proposed project will meet an institutional need to improve the manner in which JHBMC's current oncology service offerings are provided and adding radiation therapy to the service mix will undoubtedly improve the hospital's ability to establish a larger base of demand for these services.

As noted, JHBMC could implement this project without CON approval, if it is willing to forego the potential for substantive rate increases based on the project's cost impact. The questionable need equation in this case, to a large extent, must be viewed in the context of the numerous radiation therapy sites that already exist and were developed without regulatory oversight. Denying the ability of JHBMC to add radiation therapy to its suite of cancer care services because it is proposing to do so after most other hospitals have already taken this step, on an unregulated basis, raises issues of equity and fairness in the regulatory process.

Staff believes that, given these circumstances, the applicant should not be denied an opportunity to improve and augment it cancer care facilities as proposed, based on this review criterion.

C. Availability of More Cost-Effective Alternatives

COMAR 10.24.01.08G(3)(c)Availability of More Cost-Effective Alternatives.
The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

As previously outlined in the discussion of COMAR 10.24.10.04(B) (5), the Project Review Standard for Cost-Effectiveness, the applicant described its operational objectives and the project alternatives considered, including the reasons for their rejection in favor of the proposed project. Staff found that JHBMC demonstrated that the proposed capital project represented the most cost effective approach to meeting the needs that the project seeks to address.

JHBMC explains that maintaining the status quo would mean that its patients requiring radiation therapy as part of their oncologic treatment would continue to be referred to either JHH or the Greenspring radiation therapy facility. JHH is located 3 miles (9 minutes) from JHBMC while Greenspring is located approximately 18 miles (24 minutes) via I-695W from JHBMC or 13.5 miles and 24 minutes via Jones Falls Expressway. The applicant argues that "(c)ancer is a multidisciplinary program, with different treatment modalities, led by different physicians, needing to be sequenced and coordinated-not having a key component of treatment on campus disrupts the continuum of care, reduces patient satisfaction, and limits the exchange of relevant medical information that would routinely occur in a true multi-specialty setting."

A lack of physical co-location of a comprehensive suite of oncology services clearly does not preclude the Hopkins Health System from establishing some elements of a continuum of cancer care. The applicant states that, in its view, JHH is reaching its capacity to provide radiation therapy and will not be able to absorb the need projected for JHBMC patients. The applicant provided data that indicates that the Greenspring site has additional radiation therapy capacity although this is less convenient that JHH for JHBMC's core service area population. Expanding capacity at JHH might be an alternative that might provide benefits in terms of greater operating scale but, obviously, does not provide the all-inclusive center approach desired by the applicant.

JHBMC states that, without this project, it will not be providing "the standard of care" offered at other Central Maryland hospitals with cancer treatment programs (i.e., full facility and service range and care that is coordinated at one site.) As previously noted, physical co-location of all cancer services is not a standard of care established by MHCC, because it does not categorically regulated any oncology services.

Staff believes that the hospital has demonstrated that the proposed project will improve the effectiveness of its delivery of oncology services. As with our consideration of the "Need" criterion, given the limited regulatory control exercised by MHCC over these facilities and services, the balance between considerations of cost and effectiveness is less clear. While the patient population's need for these facilities and services might continue to be met, albeit with less convenience and with less accommodating facilities, at a lower cost, there are also operational cost savings with respect to the services already provided by JHBMC that should be possible through development of a centralized service facility. For these reasons, we find that the applicant has demonstrated that the proposed capital project represents a cost effective approach to meeting the institutional needs for becoming a comprehensive resource center for cancer care.

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) Viability of the Proposal.
The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

The estimated project budget for this proposal is as follows

Table 13: Estimated Project Budget Johns Hopkins Bayview Medical Center

A. Use of Funds	
1. Capital Costs	
a. New Construction	
(1) Building	$8,471,469
(4) Site Preparation	877,500
(5) Professional Fees	945,924
(6) Permits	44,040
SUBTOTAL	10,338,933
b. Renovations	
(1) Building	$3,110,473
(3) Architect/Engineering Fees	356,738
(4) Permits	16,165
SUBTOTAL	$3,483,376
c. Other Capital Costs	
(1) Major Movable Equipment	$4,931,750
(2) Minor Movable Equipment	1,241,450
(3) Contingencies	1,658,096
(4) Other (Specify)	1,354,004
SUBTOTAL	$9,185,300
Total Current Capital Costs	$23,007,609
d. Inflation	$792,391
e. Capitalized Construction Interest	$1,972,215
TOTAL PROPOSED CAPITAL COSTS	**$25,772,215**
Financing Cost and Other Cash Requirements	
Loan Placement Fee	$140,890
Legal Fees (other)	49,235
Printing	788
CON Application Assist.	24,987
Other	69,322
SUBTOTAL	$285,222
3. Working Capital Startup Costs	
TOTAL USES OF FUNDS	**$26,057,437**
B. Sources of Funds For Project	
1. Cash	$6,544,525
2. Authorized Bonds	19,300,000
3. Interest Income (Gross)	212,912
TOTAL SOURCES OF FUNDS	**$26,057,437**

Source: Submission dated 10/26,2011 (DI #16), Project Budget

Availability of Financial Resources

Staff reviewed the audited financial statements, which include the accounts of the acute care hospital, the Johns Hopkins Bayview Care Center, restricted gifts and grants programs, and other specialty programs. The statements for fiscal years ending June 30, 2010 and June 30, 2009 were analyzed. These statements showed that JHBMC had cash/cash equivalents and short-term investments in the amount of $22,457,000 in 2010 and $20,223,000 in 2009. These financial statements indicate the availability of sufficient cash resources for the proposed equity contribution.

It is important to note that JHBMC is also undertaking a separate capital project, aimed primarily at expanding emergency medical facilities, that is projected to require $10.5 million in cash contributions. Viewed in isolation, these projects could be seen as limiting further projects needing equity. However, JHBMC is also part of a larger hospital system that, as an obligated group, provides broader funding potential.

Recent Financial Performance

JHBMC's most recent operational results for those services that are regulated by the Health Services Cost Review Commission are presented below:

Table 14: Johns Hopkins Bayview Medical Center
Recent Financial Performance

	Fiscal Year Ending		
	Jun-30-2008	Jun-30-2009	Jun-30-2010
REGULATED OPERATIONS ONLY			
Net Operating Revenue	$422,918,500.00	$441,163,400.00	$437,999,400.00
Net Operating Income	$9,663,237.00	$13,855,885.00	$10,271,332.00
Net Operating Margin	2.28%	3.14%	2.35%
REGULATED AND UNREGULATED OPERATIONS			
Net Operating Revenue	$480,717,400.00	$491,642,400.00	$485,304,200.00
Net Operating Income	$4,620,400.00	$1,570,434.00	$920,400.00
Net Operating Margin	0.96%	0.32%	0.19%
Operating Margin – Peer Group 4 Regulated			
Average	7.28%	6.71%	6.38%
Median	9.55%	8.61%	8.54%
Average-Operating Margin – Peer Group 4 Regulated and Unregulated			
Average	1.39%	1.27%	0.60%
Median	1.81%	1.27%	1.64%
Average-Operating Margin – State Wide Regulated and Unregulated			
State Wide Regulated and Unregulated	2.30%	2.60%	2.60%
State Wide Regulated	5.20%	5.90%	6.20%

Source: Health Services Cost Review Commission, Disclosure of Hospital Financial and Statistical Data dated September , 2011 which reports regulated and non-regulated activity as reported on the R/E Schedule of the Annual Report.

As reflected in the table above, JHBMC operating margin for services regulated by HSCRC ranged from 2.3% to 3.1% in the last three fiscal years. This was below the average performance of its peer group during this period.

Table 15: Johns Hopkins Bayview Medical Center Regulated and Unregulated Revenue

Maryland Hospitals-Statewide Average		
Year	Operating Margin	Excess Margin
2010	2.60%	3.80%
2009	2.60%	0.01%
2008	2.30%	1.40%
Johns Hopkins BMC		
Year	Operating Margin	Excess Margin
2010	0.19%	0.48%
2009	0.32%	-1.10%
2008	0.96%	0.30%
HSCRC Target Values		
	2.75%	**4.00%**

Source: Report on Financial Conditions, Fiscal Year 2010, which was published by the Health Services Cost Review Commission on September 2011, and reports financial data of the hospital corporate entity as submitted on the audited financial statements.

The financial performance of the hospital from FY 2008 and 2010 compared to the other hospitals in the State as reported by the HSCRC based on audited financial statements is outlined in the preceding table. JHBMC generated operating and excess margins which were significantly below both Statewide averages and the targets set by the Health Services Cost Review Commission during this period.

Projected Financial Performance

The applicant projected financial performance (current year dollars) of the entire hospital for fiscal years 2012 through 2019 as follows:

Table 16: Johns Hopkins Bayview Medical Center Projected Financial Performance (in 000's)

	Current	Projected						
	2012	2013	2014	2015	2016	2017	2018	2019
Inpatient Revenue	325,767	333,374	336,740	343,030	47,479	351,297	355,241	359,527
Out Patient Revenue	168,295	176,109	178,338	194,423	196,630	200,817	205,282	209,865
Gross Pt. Revenue	494,062	509,483	515,078	537,453	544,109	552,114	560,523	569,392
Allowance For Bad Debt	17,834	18,391	18,593	19,400	19,641	19,930	20,233	20,553
Contractual Allowance	56,415	58,176	58,815	61,370	62,130	63,044	64,004	65,017
Charity Care	19,990	20,614	20,840	21,746	22,015	22,339	22,679	23,038
Net Pt. Service Revenue	399,823	412,302	416,830	434,937	440,323	446,801	453,607	460,784
Other Operating Revenue	3,010	3,010	3,010	3,010	3,010	3,010	3,010	3,010
Net Operating Revenue	402,833	415,312	419,840	437,947	443,333	449,811	456,617	463,794
Salaries, Wages, Etc.	196,591	201,114	201,067	206,239	207,435	209,334	211,269	213,092
Contracted Services	115,761	115,935	116,859	120,669	122,058	123,513	124,951	126,571
Interest on Current Debt	579	2,570	2,390	2,203	1,979	1,759	1,586	1,400
Interest on Project Debt	-	-	-	2,671	2,671	2,671	2,671	2,671
Current Depreciation	26,000	30,511	32,822	35,752	38,612	41,839	45,518	49,431
Project Depreciation	-	-	-	1,750	1,750	1,750	1,750	1,750
Current Amortization	-	-	-	-	-	-	-	-
Project Amortization	-	-	-	-	-	-	-	-
Supplies	53,221	53,318	53,673	55,556	56,169	56,814	57,396	58,041
Other Expenses	-	-	-	-	-	-	-	-
Operating Expenses	392,152	403,448	406,811	424,840	430,674	437,680	445,141	452,956
Income from Operation	10,681	11,864	13,029	13,107	12,659	12,131	11,476	10,838
Operating Margin	2.67%	2.88%	3.13%	3.01%	2.87%	2.72%	2.53%	2.35%
Patient Days	98,563	104,126	104,624	106,024	107,385	108,553	109,686	110,953
Outpatient Visits	500,974	510,056	518,934	540,216	551,537	563,105	574,876	586,879
Equivalent Inpatient Patient Days (EIPD)	149,482	159,132	160,033	166,116	168,152	170,607	173,070	175,719
Net Revenue/EIPD	$2,695	$2,610	$2,623	$2,636	$2,637	$2,637	$2,638	$2,639
Expense/EIPD	$2,623	$2,535	$2,542	$2,557	$2,561	$2,565	$2,572	$2,578

Source: CON application (DI #2), Table 3, Revenues and Expenses, Entire Facility, Table 2, Statistical Projections.

On January 27, 2012, after discussions with HSCRC staff, the applicant submitted a corrected Table 1 (utilization projections) and a Table 3 revenue and expense schedule with inflation. According to the applicant, the original Table 1 submitted with both this application and a separate Cancer Program CON application incorrectly included newborn admissions within line the MSGA figures for FY2013-FY2019. The inclusion of newborns caused a significant increase projection (6%) in admissions from FY12 to FY13. With a corrected Table 1, the admission increase from FY12 to FY13 becomes 0.3% (in line with their current expectations). This adjustment also impacts the EPIA calculations which were used for the variable expense analysis.

The following table shows projected financial performance of the entire hospital, with assumed inflation, based on the corrected utilization projections:

Table 17: Johns Hopkins Bayview Medical Center Projected Financial Performance (in $ 000's)

	Current	Projected						
	2012	2013	2014	2015	2016	2017	2018	2019
Inpatient Revenue	325,767	340,901	352,071	366,694	380,778	394,567	408,860	424,496
Out Patient Revenue	168,295	180,070	186,457	207,841	215,542	225,635	236,365	247,906
Gross Pt. Revenue	494,062	520,971	538,528	574,535	596,320	620,202	645,225	672,402
Allowance For Bad Debt	17,834	18,805	19,439	20,739	21,525	22,387	23,291	24,271
Contractual Allowance	56,415	59,488	61,492	65,604	68,092	70,818	73,676	76,779
Charity Care	19,990	21,079	21,789	23,246	24,127	25,094	26,106	27,206
Net Pt. Service Revenue	399,823	421,599	435,808	464,946	482,577	501,903	522,153	544,146
Other Operating Revenue	3,010	3,100	3,193	3,289	3,388	3,489	3,594	3,702
Net Operating Revenue	402,833	424,699	439,001	468,235	485,965	505,392	525,747	547,848
Salaries, Wages, Etc.	196,591	206,100	211,264	222,317	229,991	238,729	247,862	257,644
Contracted Services	115,761	118,877	122,847	129,896	134,903	140,125	145,480	151,382
Interest on Current Debt	579	2,570	2,390	2,203	1,979	1,759	1,586	1,400
Interest on Project Debt				2,671	2,671	2,671	2,671	2,671
Current Depreciation	26,000	30,511	32,822	35,752	38,612	41,839	45,518	49,431
Project Depreciation				1,750	1,750	1,750	1,750	1,750
Current Amortization	-	-	-	-	-	-	-	-
Project Amortization	-	-	-	-	-	-	-	-
Supplies	53,221	54,780	56,660	60,261	62,755	65,387	68,060	71,010
Other Expenses	-	-	-	-	-	-	-	-
Operating Expenses	392,152	412,838	425,983	454,850	472,660	492,259	512,927	535,288
Income from Operation	10,681	11,861	13,018	13,385	13,305	13,133	12,820	12,560
Operating Margin	2.67%	2.81%	2.99%	2.88%	2.76%	2.62%	2.46%	2.31%
Patient Days	98,563	99,114	99,617	101,319	102,684	103,856	104,988	106,262
Outpatient Visits	500,974	510,056	518,934	540,216	551,537	563,105	574,876	586,879
Equivalent Inpatient Patient Days	149,482	151,468	152,374	158,746	160,809	163,247	165,682	168,319
Net Revenue/EIPD	$2,695	$2,804	$2,881	$2,950	$3,022	$3,096	$3,173	$3,255
Expense/EIPD	$2,623	$2,726	$2,796	$2,865	$2,939	$3,015	$3,096	$3,180

Source: CON application (DI #16), Table 3, Revenues and Expenses, Entire Facility, Table 2, Statistical Projections.

For FY 2012 through FY 2019 operating margins are projected to range from 2.3% to 3.0%%, near the HSCRC target of 2.75%. The applicant projects first use of this project to occur in 2015. JHBMC estimates this project will generate excess revenues over total expenses from the first year of operation, as the table below shows.

Table 18: JHBMC Projected Financial Performance- Proposed Project (in $000's)

ORIGINAL TABLE 4							
FY	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
1. Revenues							
a. Inpatient Services			4,815	5,487	6,340	7,191	8,094
b. Outpatient Services			8,950	8,274	9,175	10,086	11,138
c. Gross Patient Service							
Revenue			13,765	13,761	15,515	17,277	19,232
d. Allowable for Bad Debt			497	497	560	624	694
e. Contractual Allowance			1,572	1,571	1,772	1,973	2,196
f. Charity Care			557	557	628	699	778
g. Net Patient Care Service							
Revenues			11,139	11,136	12,556	13,982	15,564
h. Other Operating Revenues (Specify)							
i. Total Net Operating							
Revenues			11,139	11,136	12,556	13,982	15,564
2. Expenses							
a. Salaries, Wages and Professional Fees			3,692	3,776	4,268	4,766	5,313
b. Contracted Services			1,355	1,396	1,522	1,651	1,790
c. Interest on Current Debt							
d. Interest on Project Debt			1,614	1,614	1,614	1,614	1,614
e. Current Depreciation							
f. Project Depreciation			1,745	1,745	1,745	1,745	1,745
Q. Current Amortization							
h. Project Amortization							
i. Supplies			1,073	1,097	1,240	1,385	1,544
i. Other Expenses							
k. Total Operating Expense			9,480	9,629	10,390	11,161	12,006
3. Income							
a. Income from Operation			1,660	1,508	2,166	2,821	3,557
b. Non-Operating Income							
c. Subtotal			1,660	1,508	2,166	2,821	3,557
d. Income Taxes							
e. Net Income (Loss)			1,660	1,508	2,166	2,821	3,557

Source: CON application (DI #2), Table 4 page 61.

Commission staff requested additional information on the above table. JHBMC responded, stating that the table represented the revenues and expenses attributable to the Comprehensive Cancer Program. This includes additional revenue from increased outpatient and inpatient volumes, increased salaries and other operating expenses needed to provide care to these new patients, and increased debt and depreciation expense from the new construction. These values were calculated by first developing a detailed financial projection of the entire acute care hospital, utilizing a long-range financial planning model developed by KPMG. The results of this projection were used to populate the overall schedule of revenues and expenses (Table 17). JHBMC then removed the volume and capital expenses associated with the Comprehensive Cancer Program and developed a financial projection without the Comprehensive Cancer Program. The differences between these two projections were used to populate the immediately preceding schedule.

As part of it response, the applicant also provided three complementary Tables that focus specifically on the expanded Medical Oncology Clinic and the new Radiation Oncology Facility, and "Other" services. These more detailed revenue and expense projections follow.

Table 19: JHBMC Projected Financial Performance- Proposed Project (in $ 000's)

Medical Oncology Clinic							
FY	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
1. Revenues							
a. Inpatient Services							
b. Outpatient Services	30	57	103	141	181	223	267
c. Gross Patient Service							
Revenue	30	57	103	141	181	223	267
d. Allowable for Bad Debt	1	2	4	5	7	8	10
e. Contractual Allowance	3	6	12	16	21	25	30
f. Charity Care	1	2	4	6	7	9	11
g. Net Patient Care Service							
Revenues	24	46	84	114	147	181	216
h. Other Operating Revenues (Specify)							
i. Total Net Operating							
Revenues	24	46	84	114	147	181	216
2. Expenses							
a. Salaries, Wages and Professional	157	157	157	221	221	221	221
b. Contracted Services	2	3	10	14	18	21	25
c. Interest on Current Debt							
d. Interest on Project Debt	0	0	347	347	347	347	347
e. Current Depreciation							
f. Project Depreciation			375	375	375	375	375
Q. Current Amortization							
h. Proiect Amortization							
i. Supplies	1	2	3	4	6	7	8
i. Other Expenses							
k. Total Operating Expense	160	163	892	961	965	970	975
3. Income							
a. Income from Operation	-135	-117	-808	-846	-819	-790	-759
b. Non-Operating Income							
c. Subtotal	-135	-117	-808	-846	-819	-790	-759
d. Income Taxes							
e. Net Income (Loss)	$(135)	$(117)	$(808)	$(846)	$(819)	$(790)	$(759)

Source: CON application (DI #8), Table 4 page 23

Table 18: JHBMC Projected Financial Performance- Proposed Project (in $ 000's)

Radiation Oncology							
FY	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
1. Revenues							
a. Inpatient Services							
b. Outpatient Services			4,379	4,900	5,542	6,226	7,018
c. Gross Patient Service Revenue			4,379	4,900	5,542	6,226	7,018
d. Allowable for Bad Debt			158	177	200	225	253
e. Contractual Allowance			500	559	633	711	801
f. Charity Care			177	198	224	252	284
g. Net Patient Care Service Revenues			3,544	3,965	4,485	5,038	5,679
h. Other Operating Revenues (Specify)							
i. Total Net Operating Revenues			3,544	3,965	4,485	5,038	5,679
2. Expenses							
a. Salaries, Wages and Professional Fees			861	861	946	946	946
b. Contracted Services			431	497	544	595	653
c. Interest on Current Debt							
d. Interest on Project Debt			1,267	1,267	1,267	1,267	1,267
e. Current Depreciation							
f. Project Depreciation			1,370	1,370	1,370	1,370	1,370
Q. Current Amortization							
h. Proiect Amortization							
i. Supplies			366	389	418	450	486
i. Other Expenses							
k. Total Operating Expense			4,296	4,386	4,546	4,629	4,724
3. Income							
a. Income from Operation			-753	-421	-61	409	955
b. Non-Operating Income							
c. Subtotal			-753	-421	-61	409	955
d. Income Taxes							
e. Net Income (Loss)			$(753)	$(421)	$(61)	$409	$955

Source: CON application (DI #8), Table 4 page 23

Table 19: JHBMC Projected Financial Performance- Proposed Project (in $000's)

Other							
FY	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
1. Revenues							
a. Inpatient Services	1,720	3,255	4,815	5,487	6,340	7,191	8,094
b. Outpatient Services	0	0	4,467	3,233	3,451	3,637	3,854
c. Gross Patient Service							
Revenue	1,720	3,255	9,283	8,720	9,792	10,829	11,947
d. Allowable for Bad Debt	62	117	335	315	353	391	431
e. Contractual Allowance	196	372	1,060	996	1,118	1,236	1,364
f. Charity Care	70	132	376	353	396	438	483
g. Net Patient Care Service							
Revenues	1,392	2,634	7,512	7,057	7,924	8,763	9,669
h. Other Operating Revenues (Specify)							
i. Total Net Operating							
Revenues	1,392	2,634	7,512	7,057	7,924	8,763	9,669
2. Expenses							
a. Salaries, Wages and Professional Fees	289	769	2,674	2,694	3,101	3,599	4,146
b. Contracted Services	89	187	914	885	961	1,035	1,112
c. Interest on Current Debt							
d. Interest on Project Debt							
e. Current Depreciation							
f. Project Depreciation							
Q. Current Amortization							
h. Proiect Amortization							
i. Supplies	129	267	704	704	816	928	1,049
i. Other Expenses							
k. Total Operating Expense	507	1,223	4,292	4,282	4,878	5,562	6,307
3. Income							
a. Income from Operation	885	1,411	3,220	2,775	3,046	3,201	3,361
b. Non-Operating Income							
c. Subtotal	885	1,411	3,220	2,775	3,046	3,201	3,361
d. Income Taxes							
e. Net Income (Loss)	$885	$1,411	$3,220	$2,775	$3,046	$3,201	$3,361

Source: CON application (DI #8), Table 4 page 25.

The assumptions used in development of these three tables were:

1. Gross patient revenue for each project component calculation:
   a. Medical Oncology Outpatient Revenue - Current average charge per visit for Medical Oncology cost center charges only multiplied by incremental visits.
   b. Radiation Oncology Outpatient Revenue - Current HSCRC charge per Radiation Therapy RVU only multiplied by incremental RVUs calculated from incremental treatments.
   c. Other -Total Project revenue less Medical and Radiation Oncology revenue. This represents all inpatient & outpatient charges other than those specified in sections a - b above, including inpatient routine, lab, pharmacy, supplies and other ancillary.

2. Allowance for bad debt, contractual allowance and charge care use the same total project percentages of gross revenue generated by the JHBMC/KPMG projection model described above.

3. Salary and fringe benefits expense for each project component is from Medical Oncology and Radiation Oncology tables above. Other calculated as Total Project less Medical and Radiation Oncology, which represents all other areas, including administrative, routine, lab, pharmacy, supplies and other ancillary.

4. Contracted services expense for each project is allocated to each project component based on gross revenue. Other calculated as Total Project less Medical and Radiation Oncology.

5. Interest on projected debt and project depreciation is allocated to each project component based on their percentage of total project capital expense.

6. Supplies expense is based on current actual supply expense per JHBMC Medical Oncology visit multiplied by projected visits. Because JHMBC currently does not have a Radiation Oncology program, supply expense is based current actual supply expense per JHH Radiation Oncology encounter multiplied by projected encounters. Other is calculated as Total Project less Medical and Radiation Oncology.

7. Patient mix for all components is assumed to be the same as current Medical Oncology Clinic payer mix.

The "Other" component of the Comprehensive Cancer Project provides about 62% of the incremental net revenue and 53% of the total incremental operating expenses of the entire project. The largest portion of "Other" reflects increased Cancer admissions by Medicine & Surgery services. Based on FY 2011 actual performance, the average inpatient charge for Medicine and Surgical admissions with active diagnoses of cancer is projected to be $9,400 and $22,900, respectively. Incremental expenses for these patients are also included. Another reason for "Other" is that many of the services received by patients are not assigned by JHBMC's financial account structure to the cost center where the patient is physically located. In FY 2011, patients initially seen in the Medical Oncology Clinic utilized services billed in 1,074 charge codes spread over 44 cost centers. According to the applicant, 28% of the total billed charges were assigned to the Oncology Clinic. Since many patients receive chemotherapy, 61% of the charges are assigned to Pharmacy. Other charges are assigned to the cost centers that provided the services, mainly Pathology and Radiology.

Commission staff requested a review of the project's financial feasibility from HSCRC staff. That review was not available at the time of issuance of this report. Preliminarily, HSCRC has indicated that its opinion will be positive. The written opinion will be provided as soon as it is available.

Conclusion

While JHBMC is not as financially strong as most of its peer hospitals in the State and fails to meet some HSCRC target values for financial performance, it is part of a financially strong hospital system. The proposed development of the Cancer Center is projected to have a positive impact on the hospital's bottom line. The hospital is financially stable. Therefore, staff concludes that the project and JHBMC should be viewed as viable.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e), Compliance with Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

The Johns Hopkins Bayview Medical Center ("JHBMC") submitted three CON applications in recent years.

JHBMC was a co-applicant with The Johns Hopkins Hospital for a Certificate of Need issued by the Maryland Health Resources Planning Commission. Docket No. 96-24-1983, approved on April 8, 1997, was for the relocation of eighteen acute comprehensive inpatient rehabilitation beds from the Good Samaritan Hospital to The Johns Hopkins Health System Corporation; fourteen to be relocated to The Johns Hopkins Hospital, and four (4) to be relocated at the JHBMC. No conditions were applied to the approval of the project. The relocation of the beds to the JHBMC was completed on June 17, 1997. On February 16, 1998, the relocation of the fourteen (14) beds was completed at The Johns Hopkins Hospital.

On November 22,2 005, JHBMC was awarded a CON, Docket Number 05-24-2165, to expand its operating room capacity from 10 to 14 rooms, increase the capacity of its pre- and post-anesthesia care unit, and to construct new air handling infrastructure to support the expanded surgical facilities. A request for modification was approved May 10, 2007. Due to unauthorized increases in capital costs and changes to the project, the original CON was voided. JHBMC obtained a new CON for the project in February, 2009. Final first use approval was granted November 20, 2009.

While implementation of the latter project was mismanaged, it was a complex renovation project involving a unique approach to developing specialized imaging capabilities for two of the additional operating rooms and a certain amount of the cost escalation experienced was difficult to foresee when the project was initially planned. Staff does not believe this problem is a basis for denying approval to proceed with the proposed project.

F. Impact on Existing Providers

COMAR 10.24.01.08G(3)(f),)Impact on Existing Providers and the Health Care Delivery System.
An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

The proposed project's primary impact, short-term, would be on its system's own facilities with respect to radiation therapy services, with some impact on other Central Maryland facilities who receive referrals of JHBMC cancer patients for this service. However, the impact could be greater if the applicant is successful at meeting its projected utilization long-term since the number of cancer cases is declining in JHBMC's primary service area and the cancer incidence rate is declining in Central Maryland.

JHBMC Human Resources department, in collaboration with the affected clinical and support departments and the Johns Hopkins Health System, will lead recruitment efforts for additional personnel required to staff the new positions created by this project. "Generally, new professional and non-professional positions are recruited either internally through promotions or externally from the local community using a variety of sources such as advertising and collaboration with local schools and training programs. For example, JHBMC is a clinical externship site for Medix and TESST training programs, which have become a strong recruitment source for Medical Assistants. With the wide use of internet, there has been a greater geographic source for recruiting additional personnel. JHBMC has a comprehensive recruitment website (www.bayviewjobs.org) for professional and non-professional positions. JHBMC advertises with professional association websites, such as Nursing Spectrum, Advance for Nurses, and Minority Nurse. JHBMC receives approximately 45,000 applications a year.

JHBMC indicates that it has not had difficulty filling positions in recent years. The applicant notes that "(t)he radiation therapist position will be new to JHBMC and with project completion the cancer center will employ 5.0 FTEs. While this is a new position at JHBMC, across Johns Hopkins there are currently twenty-five radiation therapists employed at The Johns Hopkins Hospital and Green Spring Station operations. Included in this number are a Chief Radiation Therapist, an Assistant Chief Radiation Therapist, and a Safety Compliance Officer. In recent years radiation therapist turnover has been minimal, but when positions open, they are filled quickly with a significant number of diverse candidates." John Hopkins participates with the Radiation Therapist training program at Essex Community college.

The applicant notes that it retains therapists through professional development, including the ability to participate in cross functional work groups with medical physicists, dosimetrists, nursing, physicians, and residents, and they are encouraged to participate in Institutional Programs such as employee engagement and patient centered care. Johns Hopkins also rotates therapists for them to develop their knowledge and skills across the fleet of linear accelerators and simulators. Finally, the therapists are required to pass an annual assessment to ensure their continued development. Consequently, Johns Hopkins has been successful recruiting radiation therapists and maintaining a turnover rate that is less than five percent per year. No additional physicist or dosimetrist FTEs were included in the applicant's submission (Table 5, page 66) which may be an understatement of staffing costs. There is a general shortage of these professionals nationally. Of course, John Hopkins has a national reputation and is likely to be an attractive employer for personnel wanting to staff the proposed radiation therapy service. It is unlikely that any one provider would be inordinately impacted by personnel changes.

The following is JHBMC's average vacancy rate and turnover rates for affected positions:

Table 20: Staffing Statistics, JHBMC – FY2011

Affected Positions	Average Turnover (FY11)	Average Vacancy Rate
All Positions JHBMC	12.8%	3.9%
Patient Care Technician	17.7%	6.8%
Registered Nurse	11.0%	3.4%
Radiation Therapist	NA	NA
Patient Registrar 1 Services Coordinator	11.9%	8.3%

JHBMC costs will increase as a result of this project and thus, in general, the cost of the local and state "system" of delivering hospital services will increase. JHBMC's recent charge position relative to peer hospitals is favorable. This project may have an impact on charges of other providers should their utilization be impacted significantly by a shifting of market share.

JHBMC costs will increase as a result of this project and thus, in general, the cost of the local and state "system" of delivering hospital services will increase. JHBMC's recent charge position relative to peer hospitals is favorable. This project has the potential for increasing the unit cost of other radiation therapy services in the region, because, if successful, it will reduce their volume of service. JHH is likely to experience the greatest level of impact. With respect to other cancer services, JHBMC is expanding the capacity of services it currently provides. Impact on other facilities is likely to be less significant, for these services.

The proposed will very marginally improve geographic access to radiation therapy. It is likely to marginally increase medical/surgical bed occupancy if it serves to boost JHBMC as a service choice for cancer patients. It will increase the fixed costs of JHBMC but may improve the hospital's ability to better control its operating cost as demand for chemotherapy services increases. The likely impact of this project does not warrant consideration of denying JHBMC approval to undertake it.

V. SUMMARY AND STAFF RECOMMENDATION

Based on its review and analysis of the Certificate of Need application, the Commission staff has determined that the proposed capital project meets an institutional need of JHBMC and and is a cost-effective approach to developing a comprehensive cancer center on the JHBMC campus. It will improve the effectiveness of cancer care delivery at JHBMC. It is a viable project. Accordingly, Staff recommends that the Commission **APPROVE** the application of the John Hopkins Bayview Medical Center for a Certificate of Need to establish a comprehensive cancer center, introducing radiation therapy services, at a total estimated cost of $26,057,437.

IN THE MATTER OF	*	**BEFORE THE**
	*	
JOHNS HOPKINS	*	**MARYLAND HEALTH**
	*	
BAYVIEW MEDICAL CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 11-24-2322	*	

*** ***

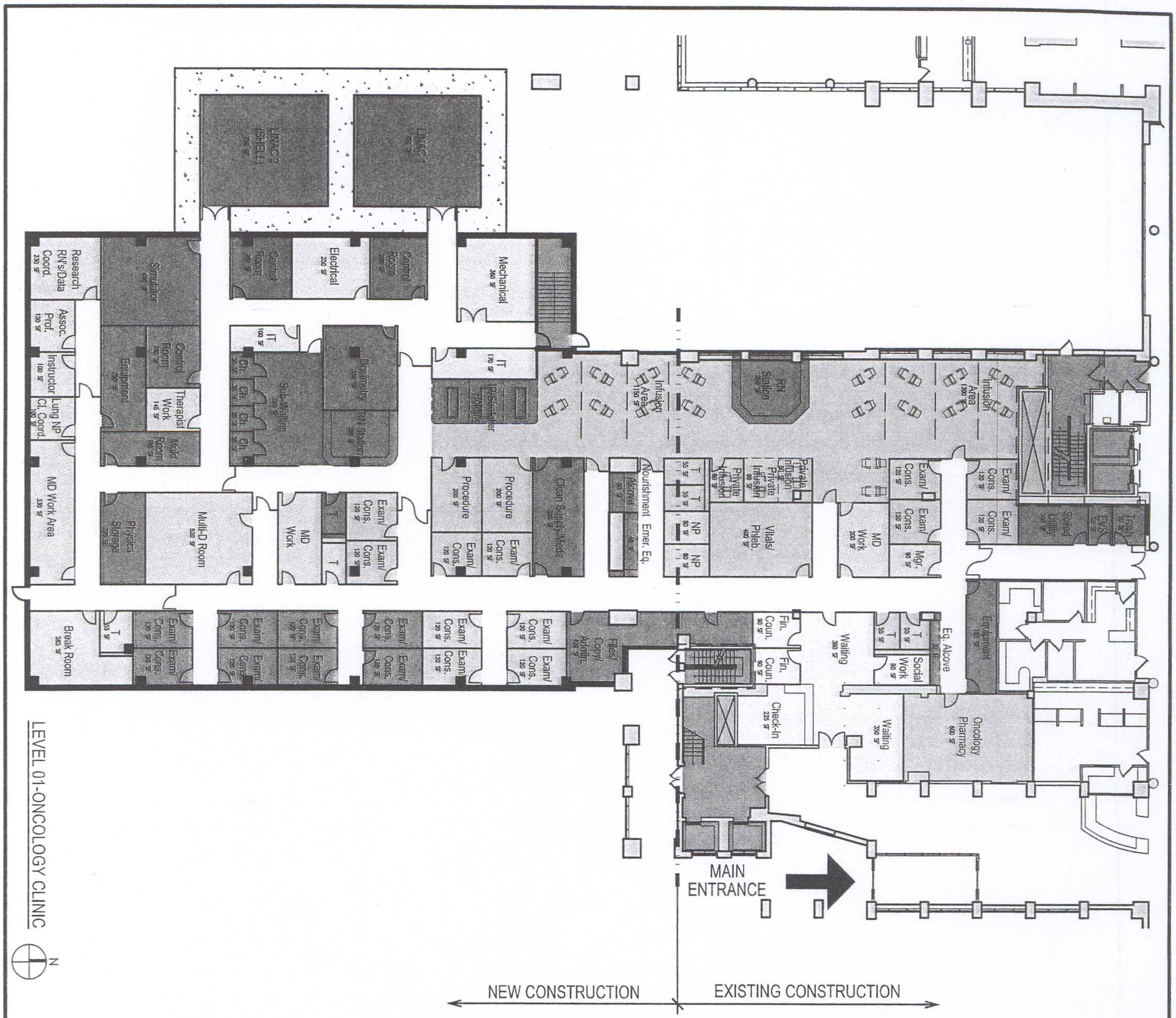
FINAL ORDER

Based on the analysis and findings in the Staff Report and Recommendation, it is this 16th day of February, 2012:

ORDERED, that the application for a Certificate of Need by Johns Hopkins Bayview Medical Center, Docket No. 11-24-2322, for the creation of a comprehensive cancer program, at a capital cost of $26,057,437 is **APPROVED.**

Appendix A

Floor Plans

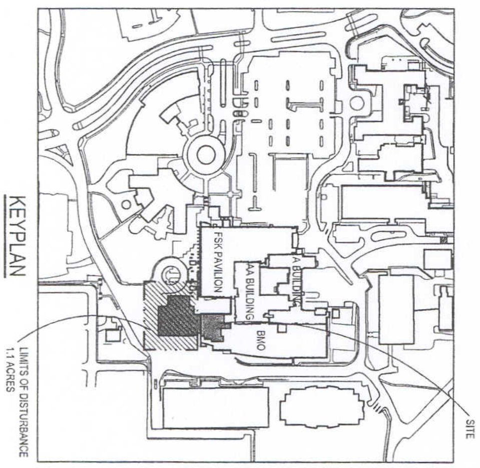


KEY

- EXISTING TO REMAIN
- HORIZONTAL CIRCULATION
- MEP SHAFTS
- VERTICAL CIRCULATION
- RADIATION ONCOLOGY
- MEDICAL ONCOLOGY
- CLINICAL SUPPORT
- STAFF SUPPORT
- PATIENT/FAMILY SUPPORT

Oncology Area Calculations

Description	Quantity	Area per (sf)
Exam Room	20	120
Linear Accelerator Bunker	2	750
Infusion Bay	21	80
Total Net Area		16,100
Department gsf		22,020



Drawing	Drawing Title	Job Title	
Sheet____of____	CONCEPTUAL DESIGN LEVEL 01 FLOOR PLAN	SIDNEY KIMMEL CANCER CENTER AT JHBMC - BMO LEVEL 01	JOHNS HOPKINS MEDICINE JOHNS HOPKINS BAYVIEW MEDICAL CENTER

Job	File name	Date	Scale	Designed by	Drawn by	Checked by
	Oncology-bmo-01.dwg	8/2/2011	1/16"=1'-0"	MS	KLB	MS

Appendix B

HSCRC Comments

(not included at this time)