Office of the President
5255 Loughboro Road, N.W.
Washington, D.C. 20016-2695
202-537-4680 Telephone
202-537-4683 Fax

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE

kwiktag ® 090 761 843

October 22, 2012

Mr. Amha W. Selassie
Director, State Health Planning and Development Agency
District of Columbia Department of Health
825 North Capitol Street
Washington, DC 20002

Re: Certificate of Need Registration Number 12-3-10

Dear Mr. Selassie:

Enclosed please find Sibley Memorial Hospital's Certificate of Need (CON) application for the Establishment of Proton Therapy Service – CON 12-3-10. We believe that this facility and equipment are vital to our growth and ability to serve this community as we work to fully integrate our oncology services with Johns Hopkins Medicine. Also included with each of the three CONs is a red binder. Documents contained in these binders include items of a competitive nature and equipment detail which fall under non-disclosure agreements. We request these documents be kept out of the public record.

We anticipate that this application will be reviewed in the November 2012 batch review of CON applications. We believe that the application is complete. However, if you or your staff need additional information, please contact Christine Stuppy, Vice President, Business Development and Strategic Planning at 202-537-4472.

We look forward to working with you through this process.

Sincerely,

Richard O. Davis, Ph.D.
President

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health

State Health Planning and
Development Agency

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[redacted]

[redacted]

Certificate of Need Application Checklist

Registration Number: 12-3-10

Applicant: Sibley Memorial Hospital

Project Title: Establishment of Proton Therapy Services

As discussed and agreed, the following questions (as checked) are to be completed on the D.C. Certificate of Need Application form for the above referenced project:

x	1.	Title
x	2.	Description
x	3.	Name and Address
X	4.	Operator (if different)
X	5.	Facility Address (if different)
x	6.	Chief Executive
x	7.	Project Representative
x	8.	Medicare Provider Number
x	9.	Medicaid Provider Number
x	10.	Submission Category
x	11.	Facility Type
x	12.	Ownership
X	13.	Review Eligibility
x	14. through 20.	Project Cost
NA	21.	Beds and Changes in Beds
x	22.	Area Served
x	23.	Location of Project Site and Ownership
x	24.	Project Target Dates
X	25.	Funding Type
X	26.	Sources of Funds
X	27.	Borrowing Details
X	28.	Facility Revenue (include all years before project completion)
X	29.	Facility Expenses (include all years before project completion)
X	30.	Facility Payment Mix
X	31.	Revenue Sources
X	32.	Facility Admissions (include all years before project completion)
X	33.	Facility Patient Days (include all years before project completion)
X	34.	Facility Average Length of Stay (include all years before project completion)
X	35.	Facility Occupancy (include all years before project completion)
X	36.	Facility Average Charge Per Patient Day (include all years before project completion)
NA	37.	Facility Newborn Nursery Utilization (include all years before project completion)
X	38.	Facility Non-Inpatient Utilization (include all years before project completion)

X	39.	Project/Service Utilization and Financial Information (include all years before project completion)
X	40.	Project/Service Revenues (include all years before project completion)
X	41.	Project/Service Surplus/Deficit (include all years before project completion)
X	42.	Project/Service Expenses (include all years before project completion)
X	43.	Personnel
X	44.	Staffing
X	45.	Major Equipment
X	46.	Current Equipment Used
X	47.	Other Equipment
x	48.	Description of Facility
x	49.	Consistency with Plans
x	50.	Facility Plan
x	51.	Population Needs
NA	52.	Reductions, etc.
x	53.	Use by Medically Underserved
x	54.	Free Care
x	55.	Access Means
X	56.	Other Providers
x	57.	Alternatives Considered
x	58.	Ancillaries
x	59.	HMO Needs
x	60.	Research Needs
x	61.	Training Programs
x	62.	Health Professional Schools
x	63.	Nonresident Use
x	64.	Economic Impact
x	65.	Other Approvals
x	66.	Accessibility
X	67.	Alternatives to Inpatient Care
X	68.	Consumer Grievances
X	69.	Linkages
X	70.	Relationships
X	71.	Quality
X	72.	Construction Methods
x	73.	ANC Contacts
x	74.	Consumer Support
x	All Certifications	

The SHPDA reserves the right to require responses to questions not indicated above if during the course of a completeness review it is determined on the basis of information in the application as submitted that other questions specified in the form are relevant.

Signatures: Thomas M'C (SHPDA Representative) Christine M Stuppy (Applicant Representative)

Dates: July 10, 2012 July 10, 2012

DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
Telephone: (202) 442-5875

For SHPDA Use Only
Date Received: _____

APPLICATION FOR CERTIFICATE OF NEED
Registration No. 12-3-10

APPLICANT'S SUMMARY INFORMATION

PART ONE—QUANTITATIVE INFORMATION

1. Project Title: **Establishment of Proton Therapy Services**

2. Brief Project Description:

Sibley requests to build a facility to house a four gantry proton therapy unit to bring Proton Therapy to the Washington Region. This unit will bring to our region technology that spares healthy tissue for the purpose of treating adults with brain, spine, and ocular tumors. The facility will also treat adults with head and neck tumors, sarcoma, and lung cancer patients, as well as pediatric patients. It is anticipated that one gantry will be dedicated to pediatric patients. Additionally, one gantry will be research and educationally focused.

The proton facility will be located on the northwest corner of Sibley's property bounded by Little Falls Road to the north, the existing service drive to the south, the new service drive and ambulance entrance for the New Sibley project to the east and the parking garage to the west.

Specifically, it will be sited on the east end of the existing pre cast parking garage. The footprint is approximately 20,000 sq ft and will be accessed by removing the precast "double tees" that currently form the parking deck. Grade is achieved at the site by removing one layer of double tees (see attached drawings **Appendix 23A-C**).

The facility will be at the west end of the circulation spine that connects to the first floor of the New Sibley. Most of the first floor of the New Sibley will be dedicated to Oncology facilities. To access the proton facility, one would proceed on a short walk westward from the New Sibley Lobby, traversing the medical oncology department and crossing a short bridge over the new service drive .

This site was chosen after a careful study of several possible locations. We chose this one because of it's convenient location to the new Oncology facilities and the fact that the construction and operation of this facility will be on the north side of the property and will not be visible nor will it impact the neighborhood. In addition the footprint for the building is readily accessible by minor modifications to the existing pre cast parking structure.

3. Applicant's Name and Mailing Address:

   Sibley Memorial Hospital
   5255 Loughboro Road, NW
   Washington, D.C. 20016

4. Name of Facility Operator (if different than 3): **Same**

5. Address of Facility(s) where service is to be provided (if different than 3): **Same**

6. Applicant's Chief Executive Officer or Administrator: **Richard O. Davis, President**

7. Project Representative: Person to whom questions should be address (not the person identified in response to question six unless that person prepared the application):

   Christine M. Stuppy, Vice President, Business Development and Strategic Planning. Telephone: 202/537-4472

*DO NOT ATTEMPT TO COMPLETE THIS APPLICATION WITHOUT FIRST CONSULTING WITH THE SHPDA STAFF PERSON ASSIGNED TO THIS PROJECT COMPLETING A "CERTIFICATE OF NEED CHECKLIST," WHICH SPECIFIES WHICH QUESTIONS MUST BE ANSWERED.

8. Facility's Medicare Provider Number: : **090005** Psychiatric: **095005**

9. Facility's Medicaid Provider Number: **Inpatient: 01900050 Outpatient: 0490050 Emergency Room: 0390050**

10. Category of Submission:

A. Qualifying Capital Expenditures and Acquisitions:

X a. Capital expenditure over $2,000,000;
___ b. Other acquisitions (by lease, donation, etc.) which have fair market value over $2,000,000;
___ c. Capital expenditure for major medical equipment over $1,300,000;
___ d. Other acquisitions (by lease, donation, etc.) of major medical equipment which have fair market value of over$1,300,000.

B. Capital Expenditure in any amount to:

___ a. increase beds (as regulated by law);
___ b. decrease beds (as regulated by law);
___ c. relocate beds (as regulated by law);
___ d. redistribute bed categories;
___ e. provide a new service;
___ f. terminate a service.

C. Acquisition by individual provider or group practice of major medical equipment.

D. New institutional health service:

___ a. new health care facility;
___ b. new home health facility;
___ c. other service not offered by the applicant on a regular basis within 12 months of the proposed offering date;
___ d. increase, decrease or relocation of renal dialysis stations;
___ e. Acquisition of facility or equipment previously acquired under HMO exemption.

11. Type of Facility (check most appropriate)

a. Hospital (applying for inpatient services-specify license type)
___ 1. General license
___ 2. Special license (specify type)

__X__ b. Hospital (applying for outpatient services)
___ c. Skilled Nursing Facility
___ d. HMO
___ e. Other Ambulatory Health Facility (free standing)
___ f. Home Health Agency (free standing)
___ g. Ambulatory Surgical Facility
h. Other, specify _____

12. Ownership of Facility:

A. All Proposals:

__X__ a. Non-Profit
___ b. For Profit
___ c. Government

B. HMO Proposals: (Complete this application only if the project is not exempt from CON Review. Consult with SHPDA staff for details). **N/A**

C. Type of Ownership:

___ a. Public
___ b. Individual Owner
___ c. Partnership (attach certified copy of partnership agreement)
__X__ d. Corporation (attach copy of corporate charter and articles of incorporation; if affiliated with other corporations, explain relationship in an attachment).

SEE APPENDIX 12 FOR CORPORATE CHARTER, ARTICLES

13. Do you claim eligibility for:

___ a. Expedited Review

If you do claim eligibility for expedited review, attach an explanation of how the project meets the requirements outlined in the law.

14. Cost for Pre-development (includes site acquisition cost, site preparation cost, architect and engineering fees, cost of permits, etc.)

Total **$ 6,500,000**

15. Project Financing Costs and Other Cash Requirements:

A.	Loan Placement Fees	$ 600,000
B.	Bond Discount	$_____
C.	Legal Fees, Printing, etc.	$_____
D.	Consultant Fees	$_____
E.	Liquidation of Existing Debt	$_____
F.	Debt Service Reserve Fund	$_____
G.	Principal Amortization Reserve Fund	$_____
H.	Capitalized Construction Interest (Net)	$ 1,000,000
I.	Other – Tax Exempt Bond Financing Costs	$ 2,000,000
	Total:	**$3,600,000**

16. Physical Plant Costs (Estimate)

A.	Construction of new and Replacement	$47,200,000*
B.	Expansion of Facility	$_____
C.	Renovation of Facility	$_____
D.	Replacement of Facility^(see note below)	$1,700,000

^This project will require modifications to an existing parking garage.

E. Lease of Existing Facility $_____
   a. Fair Market Value if Purchased
   b. Annual Lease Cost
   c. Number of Years _____

   **do not include in the total for Question 16*

F. Other Acquisition of Existing Facility
   a. Fair Market Value of Facility $_____
   b. How acquired?
   ___ i. simple purchase;
   ___ ii. stock transfer;
   ___ iii. donation;
   ___ iv. other (specify);

G. Closure of Facility $_____

H. Other (specify) Land (Equity) $ 2,000,000

TOTAL: **$50,900,000***

*Does not include contingency costs of $6.6 Million which are included below in question 19

17. Equipment Costs (check all that are applicable)

A. Type of Acquisition

X a. New
___ b. Replacement
___ c. Addition to Current Equipment of Same Type

B. How Acquired

X a. Purchased: Total Purchase Cost $59,300,000
___ b. Leased
i. If leased, Fair Market Value $_____
ii. Lease Cost $_____
iii. Number of Years _____

do not include in total for Question 17.

___ c. Donated, Fair Market Value $_____

TOTAL: **$59,300,000**

18. Costs Related to Change in Service Including Required Staff Training and Related Travel etc.

A. Type of Change in Service

X a. New Service $ 3,000,000
___ b. Expansion $_____
___ c. Reduction $_____
___ d. Termination $_____
___ e. Consolidation $_____
___ f. Relocation $_____
___ g. Other (specify) $_____

B. Explain Costs Briefly

Costs listed in item 18A. refer to the working capital (salaries, training, travel, operating, marketing, etc.) related to new service start-up costs.

TOTAL: **$3,000,000**

19. Contingency Costs (attach explanation) **$6,600,000**

The project contingency cost was based on 10% of construction, design & soft costs, and 5% of equipment costs.

20. TOTAL CAPITAL (PROJECT) EXPENDITURE
(Add Totals of Questions 14,15,16,17,18, 19)

GRAND TOTAL CAPITAL(Project): $129,900,000

Note

- The project total was reconciled to exclude the "Loan Placement Fees" and "Other – Tax Exempt Bond Financing Costs" (total of $2,600,00). The project total was reconciled because not all of the financing costs are capitalized.

21. Beds and Changes in Beds: Question not applicable per the CON Checklist

Category of Beds	A. No. of Beds Two Yrs Before	B. Current No. of Beds	C. No. of Beds at Completion	D. Net Change B. to C.	E. Net Change A. to C.
A. Medical Surgical					
B. Coronary Care					
C. OB/GYN (GYN)					
D. OB/GYN Swing					
E. Normal and Interm. Neonatal*					
F. Neonatal Intensive Care					
G. Pediatrics					
H. Psychiatric					
I. Alcoholism, Chem. Dependency					
J. Intensive Care					
K. Extended Acute Care					
L. Medical Surgical/ Skilled Nursing Swing					
M. Skilled Nursing (SNF)**					
N. Intermediate Care (ICF)*					
TOTAL					
Number of Licensed Bed***					

22. Geographic Area to be Served

For the purposes of this application, we have determined three market areas from which we expect to see patients. They are as follows:

The Regional Service Area (RSA) – The market is defined as all counties that are within a 100 mile radius of Sibley Hospital. Due to the high investment, complexity, and sub-specialization of the technology, this geography best represents the regional population, who would be served by this limited oncology treatment resource. As the Academic Proton Center for Johns Hopkins Medicine, this market is inclusive of all Johns Hopkins Health System primary, acute, tertiary, and quaternary providers and of all Johns Hopkins Affiliates and strategic clinical and research partners. This geographic area includes a population of 14.3 million people. It is projected that 70% of the proton therapy patients will be generated by this RSA.

The Other Domestic Service Area (ODSA) – This market is defined by all other domestic market areas not included in the above RSA. This market was determined by using the historical experience of Johns Hopkins, where 19% of inpatients seeking care come from beyond 100 miles radius. These patients seek expertise and treatment by the Johns Hopkins University sub-specialized faculty and physicians

International Service Area (ISA) – This market is defined as markets outside of the United States. The Sibley Proton Center anticipates seeing 10% of patients from international locations.

Included in **Appendix 22A** is a map showing the RSA area as defined above. Included in **Appendix 22B** is a reference map, showing all operational US proton therapy centers.

These areas are explained in further detain in the response to question 51.

23. Location of the Project Site and Ownership

A. Site Address

5255 Loughboro Road, NW
Washington, D.C. 20016

B. Describe Site:

The proton facility will be located on the northwest corner of Sibley's property bounded by Little Falls Road to the north, the existing service drive to the south, the new service drive and ambulance entrance for the New Sibley project to the east and the parking garage to the west.

Specifically, it will be sited on the east end of the existing pre cast parking garage. The footprint is approximately 20,000 sq ft and will be accessed by

removing the precast "double tees" that currently form the parking deck. Grade is achieved at the site by removing one layer of double tees (see attached drawings of location of site included in **Appendix 23A-C)**

Official lot and square as follows: (Square 1448-N lot 26) in Ward 3 of the District of Columbia.

C. Is the site properly zoned?

__X__ a. Yes.
_____ b. No (If no, attach a statement of zoning status)

D. a. Site Title Held by Applicant

__X__ i. Yes. If yes, state date acquired: **JANUARY 27, 1959.**
_____ ii. No

b. Option to Purchase Held by Applicant

_____ i. Yes. If yes, state date acquired_____

(aa) Date Option Expires_____
(bb)Terms of option (attach additional sheets if necessary) ____

_____ ii. No

E. Leasehold Interest for _____ years.

F. Lease Renewable every _____ years.

G. Other (specify) _____

_____

24. Project Target Dates (may be expressed in terms of months following issuance of a Certificate of Need)

A. Financing Commitment	TBD
B. Bid Advertising	12 months after CON is received.
C. Contract Award	15 months after CON is received
D. Begin Construction	16 months after CON is received
E. Complete Construction	33 months after CON is received
F. Project Completion	47 months after CON is received

G. Attach a list of major construction milestones and dates.

See Appendix 24 for gant chart of anticipated project staging:

25. Anticipated Types of Funding (check all that apply)

A. Non-Federal
__X__ a. Tax-Exempt Bonds (For Hospital Use)
____ b. Other Non-Federal Funds (for Other than Hospital Use)

B. Federal (Specify source)

26. Source of Funds for Proposed Project:

Source of Funds	A. Total Amount of Funds	B. Funds in Hand	C. Funds Assured But Not in Hand Only	D. Funds Proposed or Requested
A. Cash (Retained Earnings)	$17,600,000			$17,600,000
B. Income from Future Operations				
C. Pledges				
D. Less Allowance for Uncollectible Funds				
E. Gifts and Bequests	$20,300,000			$20,300,000
F. Interest Income				
G. Bonds (See Q.28)	$40,000,000			$40,000,000
H. Mortgage				
I. Loans (See Q.28)				
J. Grants and Appropriations				
a.Federal				
b.D.C. Govt				
c.Other (specify)				
K. Other (specify) - Equity Investment Land (equity)	$50,000,000 2,000,000	 2,000,000		$50,000,000

The below is a timetable of the internal review and approval for the Sibley Proton Therapy Project and associated financing. This process begun shortly after the integration between Johns Hopkins and Sibley was final in November 2010. The final approval from the Johns Hopkins Medicine Board and Johns Hopkins Health System Board was received on Sunday, October 21, 2012.

November 17, 2010	Initial internal discussions of Proton start between SMH and JH about bringing Proton Therapy to SMH.
November 29, 2010	Vendor site visit to Sibley to evaluate equipment configurations and development sites on the Sibley
December 6, 2010	Vendor site visit to Sibley to evaluate equipment configurations and development sites on the Sibley Campus
March 4, 2011	Sibley Building and Grounds Committee – Presentation of Proton Concept
June 7, 2011	SMH Strategic Planning Committee of the Board – Motion to move forward to study feasibility of locating Proton Beam Therapy on Sibley's Campus
July 13, 2011	National Capital Area Planning Committee – Initial Review of concept
September 12 – 16, 2011	Site visit to Vendor headquarters to evaluate equipment and development
September 19, 2011	Sibley Memorial Hospital Strategic Planning Committee – Update on Proton Project progress.
September 30, 2011	Sibley Memorial Hospital Building and Grounds Committee – Update on Proton Project progress
October 7, 2011	Vendor site visit to Sibley to evaluate equipment configurations and development sites on the Sibley Campus
November 10, 2011	Vendor presentation to Sibley Executives
June 22, 2012	JHM Senior Executive Committee: Dean CEO & JHHS President approval to seek Board of Trustee Approval for CON submission
June 28, 2012	JHM Board of Trustees Finance Committee: Approval to move forward with the regulatory process
June 29, 2012	SHPDA Letter of Intent was filed
August 31, 2012	Sibley Board of Trustees Proton Therapy Sub-Committee is appointed
September 17, 2012	JHHS Senior Executive Committee: JHHS President approval to seek Board of Trustee Project Approval
September 20, 2012	Sibley Board of Trustees Proton Therapy Sub-Committee approval to seek Full Sibley Board of Trustee Project Approval
September 25, 2012	JHM Senior Executive Committee: Dean CEO & JHHS President approval to seek Board of Trustee Project Approval
September 26, 2012	Sibley Board of Trustees approval of the Proton Therapy Project
September 27, 2012	JHM Board of Trustees Facility Real Estate Committee (FRED) – Approval of Proton project
September 27, 2012	JHM Board of Trustees Debt Sub-Committee of the Finance Committee – Approval for the Proton Therapy Project Debt Structure
September 27, 2012	JHM Board of Trustees Finance Committee – Approval of Proton Therapy Project and the Funding Structure
October 21, 2012	Presentations to Johns Hopkins Health System and Johns Hopkins Medicine Boards of Trustees – Approval of Proton Therapy Project and Funding

27. Complete the following for all borrowings (see question 26-G, H and I)

Lender/Bond Issue Issue	Amount	Rate of Interest	Annual Payment	Maturity Date
A. Tax Exempt Serial Bond	$40,000,000	2.5%	$10,792,206	2021
B.				
C.				
D.				
E				

QUESTIONS 28 THROUGH 29, FINANCIAL STATEMENTS

TABLE 28 Revenues – Entire Facility, Source: Audited Financial Statements and Internal projections CY 2010 - FY 2020.
TABLE 29 Expenses – Entire Facility, Source: Audited Financial Statements, and Internal Projections CY 2010 – FY 2020

QUESTIONS 30 THROUGH 31, PATIENT/REVENUE MIX

TABLE 30 Total Facility Patient Mix
TABLE 31 Revenues Source - Total Facility

QUESTIONS 32 THROUGH 38, UTILIZATION STATISTICS

TABLE 32 Inpatient Admissions.
TABLE 33 Patient Days.
TABLE 34 Average Length of Stay – In Days.
TABLE 35 Occupancy.
TABLE 36 Average Charge Per Patient Day.
TABLE 37 Newborn Nursery Utilization. - **Question not applicable per CON checklist**
TABLE 38 Non-Patient Utilization.

OPERATING PROJECTIONS RELATED SPECIFICALLY TO PROPOSED PROJECT – Included in Red Binder

TABLE 39 Project Related Utilization and Financial Information.
TABLE 40 Project-Service Related Revenues
TABLE 41 Project-Service Related Revenues
TABLE 42 Project-Service Related Expenses

Question 28
SIBLEY MEMORIAL HOSPITAL
REVENUE - ENTIRE FACILITY OR AGENCY

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A	Inpatient Services	$ 258,462,622	$ 260,117,768	$ 268,172,959	$ 293,031,294	$ 311,912,250	$ 331,998,565	$ 360,872,502	$ 387,875,919	$ 416,924,324	$ 448,144,641	$ 481,734,291
B	Outpatient Services	$ 206,075,676	$ 215,475,695	$ 231,046,183	$ 245,839,767	$ 265,874,493	$ 287,546,779	$ 319,859,310	$ 410,714,724	$ 474,492,535	$ 530,444,264	$ 584,528,804
C	Total Patient Service Revenues (C=A+B)	$ 464,538,298	$ 475,593,463	$ 499,219,142	$ 538,871,061	$ 577,786,743	$ 619,545,344	$ 680,731,812	$ 798,590,643	$ 891,416,859	$ 978,588,905	$ 1,066,263,095
D	Allowance for Bad Debts	$ 7,128,956	$ 7,225,295	$ 7,565,990	$ 8,335,737	$ 8,725,587	$ 9,353,730	$ 10,273,343	$ 11,147,668	$ 12,098,231	$ 13,131,481	$ 14,255,157
E	Contractual Allowances	$ 242,171,216	$ 244,849,284	$ 273,212,075	$ 309,097,208	$ 337,053,480	$ 367,179,416	$ 410,365,312	$ 484,805,416	$ 546,870,703	$ 607,591,366	$ 670,598,094
F	Allowance for Free Care for Indigent	$ 6,246,667	$ 6,515,388	$ 6,727,005	$ 7,465,548	$ 7,913,481	$ 8,388,290	$ 8,891,587	$ 12,409,845	$ 14,454,542	$ 15,975,026	$ 17,255,366
G	Allowance for Professional or Admin. Courtesy											
H	Net Patient Service Revenues (H=C-(D+E+F+G))	$ 208,991,459	$ 217,003,496	$ 211,714,072	$ 213,972,568	$ 224,094,195	$ 234,623,908	$ 251,201,570	$ 290,227,715	$ 317,993,383	$ 341,891,032	$ 364,154,476
I	Other Revenues	$ 45,086,778	$ 47,642,062	$ 47,713,855	$ 48,430,753	$ 50,610,304	$ 50,661,964	$ 51,384,289	$ 52,326,319	$ 53,494,492	$ 55,239,938	$ 57,145,491
J	Total (J=H+I)	$ 254,078,237	$ 264,645,558	$ 259,427,927	$ 262,403,321	$ 274,704,499	$ 285,285,872	$ 302,585,859	$ 342,554,034	$ 371,487,875	$ 397,130,969	$ 421,299,968

source: REV-EXP-SMH

Question 29.
SIBLEY MEMORIAL HOSPITAL
EXPENSES - ENTIRE FACILITY OR AGENCY

Sibley Memorial Hospital does not prepare its financial information in a format similar to the outline provided for this question. The following format is used by Sibley to report monthly and yearly results and is in accordance with GAAP accounting standards.

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
OPERATING EXPENSES												
A	Salaries Wages & Benefits	$ 128,981,159	$ 129,021,045	$ 134,227,969	$ 137,275,882	$ 140,675,230	$ 145,128,346	$ 151,681,652	$ 185,286,461	$ 173,692,758	$ 181,259,147	$ 188,756,361
B	Purchased Services Total	$ 30,127,379	$ 31,817,146	$ 37,349,376	$ 48,516,034	$ 57,290,246	$ 59,462,990	$ 60,663,426	$ 53,846,028	$ 62,099,005	$ 64,929,460	$ 68,043,056
C	Supplies	$ 42,945,075	$ 43,554,060	$ 43,060,380	$ 44,534,352	$ 46,622,652	$ 48,742,648	$ 53,048,886	$ 58,599,954	$ 62,118,558	$ 65,627,068	$ 69,144,873
D	Interest	$ 4,276,059	$ 3,813,409	$ 4,857,792	$ 5,322,414	$ 4,523,943	$ 5,100,659	$ 5,058,442	$ 13,358,115	$ 12,556,599	$ 12,609,061	$ 12,114,497
E	Depreciation and Amortization	$ 15,930,947	$ 15,577,503	$ 15,346,787	$ 19,875,447	$ 20,766,171	$ 22,426,171	$ 30,598,671	$ 47,021,581	$ 49,284,915	$ 51,332,415	$ 53,199,915
F												
G												
H												
	Total Operating Expenses	$ 222,260,619	$ 223,783,163	$ 234,842,304	$ 255,524,129	$ 269,878,242	$ 280,860,814	$ 301,051,078	$ 358,112,139	$ 359,751,835	$ 375,757,151	$ 391,258,701

source: REV-EXP-SMH

Question 30.

SIBLEY MEMORIAL HOSPITAL

TOTAL FACILITY INPATIENT MIX

These percentages based on number of patients, not on percent of revenues:

		Year FY2012	% of Patients, Projected Year of Operation FY2017
A.	Medicare Patients	**39.0%**	**37.9%**
B.	Medicaid Patients	**1.7%**	**2.7%**
C.	Blue Cross Patients	**28.8%**	**29.1%**
D.	Other Insurance Patients	**3.8%**	**3.0%**
E.	HMO Patients	**22.2%**	**22.7%**
F.	Self-Pay Patients	**3.2%**	**3.0%**
G.	Free Care Patients	**1.3%**	**1.6%**
H.	Other Patients (specify)		
	TOTAL A through H equals	**100.0%**	**100.0%**

NOTES: Patient mix for Sibley Memorial Hospital is expected to remain relatively constant throughout the duration of this proposed project and first year of operation. 2004 Cases do not include normal newborns, or rehab patients

Question 31.

SIBLEY MEMORIAL HOSPITAL

REVENUES SOURCE: Total Facility

		Year FY2012	First Year of Project Operation FY2017
A.	Patient Service Revenue	**86%**	**88%**
B.	Other Revenues	**14%**	**12%**
	Total A and B equals	**100%**	**100%**

NOTE: Other Revenues exclude investment income.

Question 32
SIBLEY MEMORIAL HOSPITAL
INPATIENT ADMISSIONS

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A	Medical/Surgical/Intensive Care	7,335	7,183	6,743	7,000	7,035	7,070	7,317	7,463	7,612	7,764	7,919
B	Coronary Care	-	-	-	-	-	-	-	-	-	-	-
C	OB/GYN	3,495	3,548	3,519	3,632	3,632	3,632	3,777	3,834	3,892	3,950	4,009
D	OB/GYN Swing	-	-	-	-	-	-	-	-	-	-	-
E	Norm & Intermediate Neonatal	3,531	3,577	3,545	3,641	3,641	3,641	3,787	3,844	3,902	3,961	4,020
F	Neonatal ICU	-	-	-	-	-	-	-	-	-	-	-
G	Pediatrics	-	-	-	-	-	-	-	-	-	-	-
H	Psychiatric	599	580	556	590	593	596	599	602	605	608	611
I	Alcohol, Chem Dependency	-	-	-	-	-	-	-	-	-	-	-
J	Rehabilitation	-	-	-	-	-	-	-	-	-	-	-
K	Extended Acute Care	-	-	-	-	-	-	-	-	-	-	-
L	Med-Surg/SNF Swing	-	-	-	-	-	-	-	-	-	-	-
M	Skilled Nursing	1,174	1,156	1,046	1,146	1,152	1,158	1,164	1,170	1,176	1,182	1,188
N	Intermediate Care	-	-	-	-	-	-	-	-	-	-	-
	TOTAL	16,134	16,044	15,409	16,009	16,053	16,097	16,644	16,913	17,187	17,465	17,747

NOTES:

Question 33
SIBLEY MEMORIAL HOSPITAL
INPATIENT PATIENT DAYS

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A	Medical/Surgical/Intensive Care	33,602	31,124	27,910	28,700	28,844	28,987	30,000	30,598	31,209	31,832	32,468
B	Coronary Care	-	-	-	-	-	-	-	-	-	-	-
C	OB/GYN	10,309	10,361	10,388	10,714	10,714	10,714	11,142	11,310	11,481	11,652	11,826
D	OB/GYN Swing											
E	Norm & Intermediate Neonatal	10,342	10,429	10,413	11,054	11,054	11,054	11,497	11,670	11,846	12,026	12,205
F	Neonatal ICU	-	-	-	-	-	-	-	-	-	-	-
G	Pediatrics	-	-	-	-	-	-	-	-	-	-	-
H	Psychiatric	5,072	5,829	6,228	6,338	6,370	6,402	6,435	6,467	6,499	6,531	6,564
I	Alcohol, Chem Dependency	-	-	-	-	-	-	-	-	-	-	-
J	Rehabilitation	-	-	-	-	-	-	-	-	-	-	-
K	Extended Acute Care	-	-	-	-	-	-	-	-	-	-	-
L	Med-Surg/SNF Swing	-	-	-	-	-	-	-	-	-	-	-
M	Skilled Nursing	14,700	14,971	14,117	14,741	14,818	14,895	14,973	15,050	15,127	15,204	15,281
N	Intermediate Care	-	-	-	-	-	-	-	-	-	-	-
	TOTAL	74,025	72,714	69,056	71,547	71,800	72,052	74,047	75,095	76,162	77,245	78,344

NOTES:
a .5% increase in years 2011 - 2018

Question 34

SIBLEY MEMORIAL HOSPITAL

INPATIENT AVERAGE LENGTH OF STAY - IN DAYS

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A	Medical/Surgical/Intensive Care	4.58	4.33	4.14	4.10	4.10	4.10	4.10	4.10	4.10	4.10	4.10
B	Coronary Care	-	-	-	-	-	-	-	-	-	-	-
C	OB/GYN	2.95	2.92	2.95	2.95	2.95	2.95	2.95	2.95	2.95	2.95	2.95
D	OB/GYN Swing	-	-	-	-	-	-	-	-	-	-	-
E	Norm & Intermediate Neonatal	2.93	2.92	2.94	3.04	3.04	3.04	3.04	3.04	3.04	3.04	3.04
F	Neonatal ICU	-	-	-	-	-	-	-	-	-	-	-
G	Pediatrics	-	-	-	-	-	-	-	-	-	-	-
H	Psychiatric	8.47	10.05	11.20	10.74	10.74	10.74	10.74	10.74	10.74	10.74	10.74
I	Alcohol, Chem Dependency	-	-	-	-	-	-	-	-	-	-	-
J	Rehabilitation	-	-	-	-	-	-	-	-	-	-	-
K	Extended Acute Care	-	-	-	-	-	-	-	-	-	-	-
L	Med-Surg/SNF Swing	-	-	-	-	-	-	-	-	-	-	-
M	Skilled Nursing	12.52	12.95	13.50	12.86	12.86	12.86	12.86	12.86	12.86	12.86	12.86
N	Intermediate Care	-	-	-	-	-	-	-	-	-	-	-
	Grand Mean Length of Stay	4.59	4.53	4.48	4.47	4.47	4.48	4.45	4.44	4.43	4.42	4.41

ALOS calculated using days over Discharges

Question 35
SIBLEY MEMORIAL HOSPITAL
OCCUPANCY

		Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A	Medical/Surgical/Intensive Care	35%	32%	31%	32%	32%	33%	36%	40%	40%	41%	42%
B	Coronary Care	-	-	-	-	-	-	-	-	-	-	-
C	OB/GYN	78%	79%	62%	64%	64%	64%	64%	62%	63%	64%	65%
D	OB/GYN Swing	-	-	-	-	-	-	-	-	-	-	-
E	Norm & Intermediate Neonatal	69%	70%	56%	59%	59%	59%	60%	59%	60%	61%	62%
F	Neonatal ICU	-	-	-	-	-	-	-	-	-	-	-
G	Pediatrics	-	-	-	-	-	-	-	-	-	-	-
H	Psychiatric	50%	57%	61%	62%	62%	63%	65%	68%	68%	69%	69%
I	Alcohol, Chem Dependency	-	-	-	-	-	-	-	-	-	-	-
J	Rehabilitation	-	-	-	-	-	-	-	-	-	-	-
K	Extended Acute Care	-	-	-	-	-	-	-	-	-	-	-
L	Med-Surg/SNF Swing	-	-	-	-	-	-	-	-	-	-	-
M	Skilled Nursing	89%	91%	86%	90%	90%	91%	91%	92%	92%	93%	93%
N	Intermediate Care	-	-	-	-	-	-	-	-	-	-	-
	TOTAL	49%	48%	46%	47%	48%	48%	51%	53%	54%	55%	55%

NOTE: The occupancy statistics are based on the number of licensed beds versus operating (available) beds., thus causing occupancy to be understated.

Question 38
SIBLEY MEMORIAL HOSPITAL
NON-INPATIENT UTILIZATION

	Actual CY2010	Actual FY2011	Actual FY2012	Budget FY2013	Projected FY2014	Projected FY2015	Projected FY2016	Projected FY2017	Projected FY2018	Projected FY2019	Projected FY2020
A Emergency	24,194	26,167	29,919	32,423	33,071	33,732	35,419	36,659	37,942	39,270	40,644
B Outpatient Dept.	61,084	62,781	63,247	67,881	69,267	70,683	74,155	88,780	97,451	103,970	109,478
C Home Health Care											
D Hospice Home Care											
E Chronic Kidney Disease Facility 1. Outpatient staff assisted in facility, Chronic Maintenance Hemodialysis											
2. Outpatient self care in facility, Chronic Maintenance Hemodialysis											
3. Outpatient self care in facility, Intermittent Periotoneal Dialysis, including Training											
4. Training for Home Intermittent Peritoneal Dialysis											

Note: Outpatient volume includes: Physicial Therapy, all radiological exams, cardiopulmonarty exams, outpatient surgery, endoscopy, and Labor and Delivery procedures.

Questions 39 – 42

in SEPARATE binder

43. Personnel for Project: Proton Therapy Services

Provide a list of the type and number of full-time equivalents (FTEs) and estimated annual salary of all personnel required to staff the new or expanded facility or service and identify the sources from which you intend to obtain the required personnel. Include current staff and volunteers if applicable.

Year 4 FTE Projections - 100% Capacity
Steady State

Department	Personnel Category	Number of FTE's	Salary Expense	Average Salary per FTE	Source of Personnel
JHU - School Of Medicine	Physician Faculty	4.5	1,417,948.50	$315,100	See Notes Below
	Physics & IT	9.0	1,655,455.00	183,939	
	Dosimetry	5.0	619,390.00	123,878	
	Nurse Practitioner	4.0	450,464.00	112,616	
Sibley Rad Onc	Therapists	18.7	2,002,326.40	107,076	
	Nursing	6.9	664,279.20	96,272	
	Clinical Associates	4.0	184,692.00	46,173	
	Billing & PSC	7.0	320,956.00	45,851	
	Administrator	1.0	135,140.00	135,140	
	Administrative Assistants	3.0	152,031.00	50,677	
	Analysts	4.0	281,540.00	70,385	Financial, Regulatory, & IT
	Clinical Trials	2.0	144,149.00	72,075	Research RN & Data Coordinator

Notes:

1. The Sibley Proton Therapy Center is projected to take 4 years to ramp up to 100% capacity, so Year 4 data were used in response to Question 43.
2. Salaries do not include benefits or incentive compensation
3. All positions are incremental and will require recruitment.
4. Staff levels indicative of full ramp up of operations which is to occur in year 4.

44A. Staffing

Explain how staffing was determined. In an attachment, describe the methodology (including the definition of FTE) used to determine the above staffing and cite any pertinent studies or programs upon which the staffing was based

Response:

An FTE is based on working 2,080 hours per year. Staffing levels and costs are based on analysis completed by Johns Hopkins Medicine and Sibley's Human Resource departments and are based on current staffing ratios and mid-point average salaries.

Clinical and operational staffing was estimated by the John Hopkins Radiation Oncology Department using physician advice, recommended protocols and feedback from existing proton therapy centers.

- Staffing projections were based on analysis completed by Johns Hopkins Medicine and Sibley Human Resources; for staffing projections by FTE and salary please see **Appendix 44B-A and Appendix 44B-B.**

44B. Staffing:
In an attachment, describe the sources available for recruiting additional personnel. Do you anticipate any difficulty in recruiting needed personnel? Why or why not?

Response:

Johns Hopkins Medicine and Sibley Memorial Hospital advertise for personnel in the Washington Post and appropriate professional and trade journals. Sibley also uses the Internet for search engine marketing and posts positions on several niche career websites as well as the District of Columbia's Department of Employment Services website. Additionally, representatives from Sibley attend local career fairs and various national association conferences. We expect these methods to be sufficient in recruiting the needed technologists given the sufficient lead-time of the project. Additionally, there is sufficient time between the potential application approval and the time at which these personnel would begin employment. As such, Sibley and Johns Hopkins do not anticipate difficulty in hiring the necessary staff.

45. List of Major Equipment – Please see Response in Separate Binder

46. Current Major Equipment to be used in New Service or Facility

Qty	Description	Annual Lease (if leased)
N/A	We do not anticipate using any current equipment for the Proton Project	

47. In an attachment, provide a general description and statement of the total value of any equipment not specified above in questions 43 and 44

Other Facility Equipment:	
• Office/Patient Room Furniture	$300,000
• IT Equipment & related infrastructure	$1,000,000

Note: the items listed above are included in total project construction costs.

ESTABLISHMENT OF PROTON THERAPY SERVICES

PART TWO -- NARRATIVE

48. Provide a reasonably full and detailed description of the facility, service(s) and equipment to be provided, as well as a justification and supporting evidence for establishing the service. This information will serve as an introduction to the proposal and to the specific questions below. The description may make reference to information supplied in response to specific questions throughout this application.

Introduction

Sibley Memorial Hospital ("**Sibley**"), a member of Johns Hopkins Medicine ("**JHM**"), seeks approval to build and establish a Proton Therapy Center in Washington, D.C. The proton facility will be located on the northwest corner of Sibley's property, bounded by Little Falls Road to the north, the existing service drive to the south, the new service drive and ambulance entrance for the New Sibley project to the east and the parking garage to the west.

This project is consistent with Sibley's history of innovation and its commitment to offer the latest life-saving services to its patient community and to the broader Washington, D.C. community. Over the last 120 years, Sibley has provided its community with the very best in clinical care through continued innovation, seeking ways to serve its patients better and being the first to provide new procedures, to invest in leading-edge technologies and to create advanced facilities. Sibley was the first to pioneer laparoscopic procedures in the Washington, D.C. Region and to provide Tomotherapy and PET/CT technology, as well as prone radiation for the accurate diagnosing, staging, and treatment of cancers. Sibley was the first in the area to build two fully integrated operating rooms featuring technologically advanced surgical equipment that provides the surgical team complete and immediate control of each OR with touch screen and voice-activated response as well as high-definition video.

When Sibley Memorial Hospital and Johns Hopkins Medicine entered into a strategic partnership a few years ago, they agreed to prioritize the growth and enhancement of several clinical services and programs. The enhancement of oncology services was specifically identified as a high priority. When the partnership was finalized in November of 2010, collaborative strategic planning around oncology services began immediately, focused on growth in new oncology services at Sibley and on the integration of the existing oncology programs with programs at Johns Hopkins. Both the Definitive Agreement between the two institutions and the Acquisition CON, registration number 10-3-2, describe the interest in this area, and state that Johns Hopkins Medicine will help Sibley make this strategic expansion a reality.

Clinical oncology is being enhanced through collaborative partnerships and programming in radiation oncology and medical oncology, providing the Sibley community with access to an expanded infusion center, the latest radiation oncology technologies and services, and to new clinical trials. Research through clinical trials across all clinical services is now standardized between Sibley and Johns Hopkins Medicine, making the infrastructure, expertise, and experience of Johns Hopkins Medicine available at Sibley to improve clinical trial access and quality.

In the short time since the Definitive Agreement was signed, the strategic partnership between Sibley and JHM has already resulted in several significant enhancements in Oncology services at Sibley. Our new Radiation Oncology Center, which opened in October of 2012, is an example of the success of this collaboration. The Oncology center offers the latest in radiation therapy technology and image guided therapy. Through collaborations between Sibley and Johns Hopkins Medical Oncology, we have jointly developed and opened an expanded Sibley Infusion Center that will be led by world renowned Johns Hopkins medical oncologists and that will provide our community physicians and patients, access to the latest advancements in cancer therapies.

Sibley and JHM are also working to collaborate in clinical trial research, which will bring innovative new therapies and clinical trial protocols to the Sibley community and to Washington, D.C. as well as real opportunities for co-development of new treatment methods at Sibley. Sibley now falls under the research umbrella of JHM with a standardized Institutional Review Board ("**IRB**") and with a new infrastructure for clinical trial management. These programs are transforming options and outcomes for our patients, and are expanding Sibley's ability to treat patients more comprehensively within the District of Columbia.

In addition, Sibley, in concert with JHM, will be implementing an integrated Electronic Medical Record ("**EMR**"). This EMR will be implemented in the summer of 2013, and it will greatly enhance our ability to seamlessly access all needed services across the JHM system, while also improving communication and collaboration among our physicians and other providers. A private practice product will also be offered to our community-based physicians to allow them access to the Sibley/JHM EMR and allow seamless transition of patient care from inpatient, outpatient and ancillary service offerings.

The Sibley Proton Project

The development of the Sibley Proton Therapy Center is an exciting next step in the collaborative expansion of oncology services at Sibley. It will create opportunities for researchers to conduct cutting-edge research, helping to answer critical questions and shape future advancements in oncology care. It will create training opportunities not just for trainees in JHM programs, but for students and trainees at several institutions across the Washington, D.C. area. Most importantly, though, this project will bring this life-saving therapy not just to the Sibley patient community, but to patients throughout Washington, D.C., from across the United States, and from other countries, including to patients in need from the Primary Service Area and the Regional Service Areas. See Response to Question 51. The development of the Sibley Proton Therapy Center will require significant investments in multi-disciplinary clinical expertise, in capital equipment, in infrastructure, and in research capabilities. The Sibley Proton Project would not be possible if Sibley were a stand-alone facility.

In fact, the Sibley Proton Project is a true collaboration of several institutions within the District of Columbia. In addition to JHM, the Sibley Proton Project will include the Children's National Medical Center (CNMC) as a strategic partner and owner of a joint-ventured proton therapy service. The pediatric proton therapy service is a critical component of the Sibley Proton Project and is the building block for a new Pediatric Radiation Oncology Service that JHM, Sibley and CNMC intend to develop at Sibley in the near future

We believe there is no more important and compelling reason justifying the addition of the Sibley Proton Project than to make it available to children with cancer. The Sibley Proton Project will facilitate pediatric proton therapy in the District of Columbia, throughout the entire Primary Service Area and Regional Service Area of the Sibley Proton Project. Moreover, the joint venture pediatric proton therapy service is a unique service in the history of the District of Columbia, because it is the first time both Sibley and CNMC have joint ventured to create a service which would be very difficult for either of them to provide individually. The need in the District of Columbia for treatment in the pediatric population is demonstrated through our volume projections. That is the reason that the equivalent capacity of one entire treatment room, out of our proposed four treatment room system, will be devoted to treating children. For CNMC, the pediatric proton therapy service represents the first time CNMC will have access to proton therapy for its patients in Washington, D.C.. Currently CNMC sends its patients requiring proton therapy outside Washington D.C. to either Massachusetts or Texas.

The Sibley Proton Project is also a partnership with Howard University ("Howard"). **(See Appendix 74D for a copy of the fully executed Memorandum of Understanding.)** While Johns Hopkins has had a long standing partnership in oncology research and training with Howard, the Sibley Proton Project extends the research partnership to proton therapy and adds advancement in education, training and clinical care. As proposed, the Howard / Sibley / JHM partnership will extend the long history in joint research by partnering in the development in proton therapy clinical trials. As part of such research, the parties will work together to develop a community based program to educate the Howard patient community as well as other minority patients about the benefits of ethical clinical trials in oncology and how clinical trials can provide access to the newest, contemporary therapies. In essence, the proposed community based program will be designed to differentiate the proton clinical trials from the negative legacy of trials such as the Tuskegee Experiment, which have given clinical trials a bad name in many communities.

The Howard partnership contemplates co-developing a clinical care program to provide proton therapy consultation and follow-up services locally within the Howard patient community. The Howard partnership will also contain an education component focused on medical residents and fellows training in proton therapy. As part of the education component, the parties will co-develop a collaborative program that will expose Howard undergraduate and graduate physics students to medical physics to encourage and support career development. . Medical Physicists are critical participants who partner with the Radiation Oncologists, nurses, radiation therapists, and medical dosimetrists to ensure the quality and safety in the delivery of radiation, to manage complex treatment techniques such as Active Breathing Control and Stereotactic Radiation, and to develop new clinical techniques and treatment protocols. Medical physicists ensure compliance with the Radiation Safety Regulations, and they verify that newly constructed shielding and newly installed radiation equipment adhere to these regulatory standards. Medical Physicists are in short supply and high demand, particularly Medical Physicists with specialized training in

proton therapy, which increases the demand for training opportunities and grows the capacity of training programs in order to fill the growing number of medical physics jobs in Radiation Oncology. The collaborative program between Howard, Johns Hopkins University, and Sibley will focus on growing the pool of qualified medical physicists, on developing a training program at Sibley where students and residents are exposed to radiation therapy and proton therapy, and on narrowing disparities in the number of African Americans and other minorities working in the field of Medical Physics.

The joint venture of Sibley, JHM, CNMC and Howard will enable the Sibley Proton Project to create an academic proton therapy center that fully realizes the tripartite mission of Johns Hopkins Medicine, which is to improve health through advances in medical education, research and clinical care, in Washington, D.C. The tripartite mission is consistent with, and indeed in this project will build upon the strong foundation of the Sibley mission: "to provide quality health services and facilities for the community, to promote wellness, to relieve suffering and to restore health as swiftly, safely, and humanely as it can be done consistent with the best service we can give at the highest value for all concerned." Each of the joint venture partners: Sibley, CNMC, Howard and JHM are critical to advance medical education, to advance research and to advance clinical care. For over 120 years, through the pursuit of the tripartite mission, Johns Hopkins Medicine has achieved tremendous success in all three areas and has been a long-established leader in the global health care community. Sibley's commitment to outstanding, caring clinical services for its community provides an excellent foundation for this project. For this type of regional service, where opportunities for training are limited and the need for clinical research is great, though, the additional pillars of research and education are essential. The tripartite mission, including the clinical care mission of Sibley, will be the foundation of the Sibley Proton Therapy Center.

At Johns Hopkins, pursuit of the tripartite mission has led to transformative discoveries that have directly benefited the patients at Johns Hopkins and the global health care community at large. Examples of these discoveries include the first protocolized use of rubber gloves in surgery, the development of renal dialysis, and the discovery of restriction enzymes which provided the basis for molecular biology and molecular medicine. The Johns Hopkins Medicine Department of Radiation Oncology scientists and clinicians continue to demonstrate the value of the tripartite mission by taking new discoveries from the lab and bringing them to the clinic for the treatment of patients. A few examples include:

- First to target radiation to tumors using antibodies.
- First to develop and treat patients with prostate cancer using prostate-specific viruses.
- First to develop and clinically translate a non-invasive immobilization for stereotactic radiosurgery.
- First to demonstrate the value of PARP (poly ADP ribose polymerase) inhibitors and radiation for the treatment of cancer.
- First to study, apply, and publish scientific research on Patient Safety within the context of complex Radiation Oncology workflows.

Proton Therapy has been proven to save lives, and to enhance the quality of life, for specific patient populations diagnosed with specific types of tumors. The explanation for this lies in the science, as described below. By aligning the goals of the Sibley Proton Therapy Center with the Johns Hopkins Tripartite Mission, JHM, CNMC, Howard and Sibley commit to continue the tradition of discovery, generating new knowledge that will ensure the most contemporary care for patients and that provides the most contemporary environment in which to educate future leaders in oncology. Committing to advance proton therapy in this way ensures that the Sibley Proton Project will lead in demonstrating the appropriate use of proton therapy in the treatment of patients with cancer.

A recent New York Times Opinion article by Dr. Ezekiel Emanuel **(Appendix 48A)** criticized the proliferation of proton therapy for the treatment of prostate cancer; we concur with Dr. Emanuel, and believe that the development of our project is completely consistent with his message. Dr. Emanuel's criticism focuses on the extended use of proton therapy for the treatment of prostate cancer without supporting evidence, and without being a part of structured clinical trials. He describes the use of proton therapy for prostate cancer as an unstudied, more expensive alternative for care with little proven incremental efficacy, where institutions are making significant returns primarily by treating prostate cancer. Our strategy around the Sibley Proton Therapy Center is that it will be research-centric and focus on discovery, clinical care, and education.

Consistent with our commitment to the rigorous study of this treatment modality, one treatment room will be devoted to research. This includes developing robust clinical trials to study efficacy, using laboratory-based research to transform the application of the treatment protocols while reducing cost, and advancing the development of the technology to deliver higher quality, safer treatments. Dr. Emanuel's message challenges the health care community to focus on evidence-based medical innovation that is cost effective to the health care delivery system. The Sibley Proton Project model directly addresses this challenge. Our research-centric model focuses on understanding comparative efficacy and biologic response of proton therapy. This knowledge will allow the Sibley Proton Therapy Center, in partnership with Johns Hopkins Medicine, CNMC and Howard to transform the conventional use of proton therapy with the goal of developing new treatment plan protocols that could be more effective and cheaper than conventional radiation alternatives.

The Challenge of Conventional Radiation Therapy

The challenge with conventional radiation therapy is that it delivers a dose of radiation through streams of energy called photons that harm healthy tissue. Proton therapy avoids exposing healthy tissues to significant amounts of radiation and the collateral damage associated with such exposure.

Photons are created when electrons interact with one another, thus resulting in a release of energy. Radiation Oncology clinicians are able to control the volume of electron interactions and the direction of the interactions, creating a photon beam that travels through a patient and delivers a radiation dose to the tissue (healthy and cancerous) with which it interacts. The Radiation Oncologist uses multiple beams that intersect at the site of the tumor in order to deliver the maximum dose possible to the tumor. Despite efforts to minimize the incidental dose of radiation delivered to healthy tissue, damage is still done to healthy tissue, and depending on the type of patient and the location of the tumor, the damage could have clinically significant impact. Patients that have the highest risk of clinically

significant impact are pediatric patients and adult patients that are being treated at or near critical organs, such as the brain, the spine, the neck, or the lung. The band of color shown in the left side of Figure 1, below, is the path of radiation that is planned for the treatment of the patient's eye tumor with conventional radiation therapy. Deep red colors indicate a high dose of radiation, and blue colors represent a lower dose. For this pediatric patient, the eye, with the diseased tissue, is receiving the highest dose, but because conventional radiation travels through the body, it is unavoidable that a significant amount of healthy tissue is also exposed to a dose of radiation. The following describes the risks to this patient from the unavoidable exposure of healthy tissue to radiation and the long term problems that could manifest.

The Pituitary Gland: The pituitary gland is responsible for the creation of various hormones in the body. The exposure to radiation for this pediatric patient could cause pituitary dysfunction. Some of the long term effects of this include:

- Lack of growth hormone causing issues of growth development;
- Reproductive deficiencies; and
- Irreversible dependence on hormone replacement through steroid therapies.

The Facial Bone: Though the exposed facial bone is not proximal to the tumor, the exposure to radiation could cause a lack of growth in these bones causing issues with facial development.

The Brain: A large segment of healthy brain tissue is exposed to the path of conventional radiation. This toxicity can cause significant issues with cognitive delay and social adjustment, which can result in an inability to effectively learn and succeed in higher education and an inability to develop a successful career. The long-term patient impact is the inability to have a high quality, functional life. This long term impact often causes collateral medical issues that would need to be managed, such as depression.

The Retina: The retina of the healthy eye is unavoidably exposed to the conventional radiation. This exposure creates a significant risk of developing retinopathy, which can lead to blurry vision and well as potential unnecessary loss in vision. There is also a significant risk that the healthy eye will experience chronic dryness requiring long term symptom management.

The Vasculature: Though the vasculature cannot be seen in this image, the blood vessels in the exposed brain create a significant risk for the patient because the radiation toxicity can cause irreversible vascular abnormalities that are prone to bleeding. If this occurs, the patient will have a higher risk of stroke.

Secondary Malignancy: Also not shown in Figure 1, the patient is at risk of developing a secondary malignancy due to the exposure of healthy tissue to conventional radiation.

The choice between defeating cancer through the use of conventional radiation and succumbing to it is usually clear for clinicians and patients. It can be a very difficult choice, though, given the significant collateral damage and associated risks. Current work in radiation therapy research and development is focused on achieving the same high rates of success in treating cancer while minimizing or eliminating the damage to healthy tissue and associated negative effects.

Radiation Therapies: The Clinical Imperative for Proton Therapy

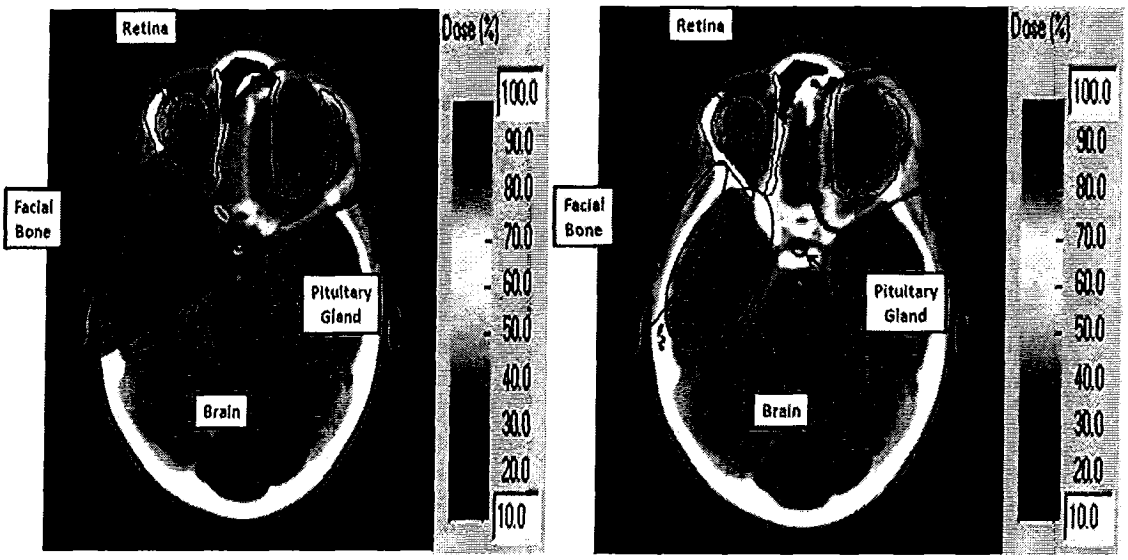
The principles of Radiation Oncology are as follows: 1.To deliver a clinically effective radiation dose to the tumor; and 2. To protect healthy tissue. These principles hold true for all forms of conventional radiation therapy that are used as a therapeutic intervention for pediatric and adult cancer patients. The principles are the foundation for the continuous development of the radiation delivery technology, which has included robotic linear accelerators, real time CT imaging, and targeting techniques that are accurate within a few millimeters. Even with these advances, though, the exposure of healthy tissue to a radiation dose cannot be avoided. This problem—weighing the therapeutic benefit against harm to healthy tissue, restricts the use and clinical impact of conventional radiation therapy.

Proton Therapy: A Safer Therapeutic Alternative

Value in proton therapy is derived from the ability to control dose distribution, and to do so better than conventional radiation therapies allow. This enhanced dose control improves cancer targeting and improves our ability to spare healthy tissues and reduce toxicities and their side effects. The advantage of proton physics is ideal for our pediatric cancer population, particularly since many of the curative patients have a long life expectancy. Clinical value of proton therapy over conventional radiation therapy is also applicable to diseases where sparing surrounding healthy tissue is critical, such as intracranial, spine, neck, abdominal, and lung tumors.

Over the past forty years, more than 50,000 patients globally have been treated with an alternative to conventional radiation therapy, called proton therapy. As described above, conventional radiation therapy relies on electrons to create photon beams of radiation that travel through the patient. Proton therapy, conversely, creates a beam of protons that is used to target and kill cancer cells. Proton therapy has a significant advantage over photon therapy. The radiation dose of the proton beam can be controlled with extreme precision, targeting nearly all the radiation to the cancer cells and only minimally exposing healthy tissue. Unlike conventional radiation photon beams, proton therapy beams do not travel through the patient—they can be directed to stop at the tumor. The right picture in Figure 1 shows the radiation dose from the proton beam radiation treatment for the same pediatric patient. The advantages of proton therapy could not be more explicit:

FIGURE 1:



- Nearly the entire proton radiation dose is deposited at the site of the tumor, which results in a higher dose of radiation to the tumor, and a dose that conforms to the shape of the tumor.

- There is no exit dose. Unlike the conventional radiation path discussed above, the proton therapy beam is stopped at the site of the tumor. In the case in Figure 1 there is no exposure to the Pituitary Gland, the healthy eye, or to the healthy facial bone. Also, the majority of the healthy brain tissue avoided any radiation dose, which also means no exposure to the vasculature in the brain.

- The risks to and long term effects of radiation treatment to the pediatric patient in this example are minimized if not completely eliminated. This patient has a significantly greater likelihood of leading a long, high quality life, free of radiation toxicity side effects.

This patient example, provided by Massachusetts General Hospital, shows that a safer, more precise radiation therapy alternative for cancer patients is possible. Providers and patients are challenged, however, to achieve optimal treatment because of a lack access to Proton Therapy. There are currently only ten centers in operation in the United States. Sibley Memorial Hospital, Johns Hopkins Medicine, Children's National Medical Center and Howard University consider the Sibley Proton Project to be a mission-centric imperative for the care of the cancer population in Washington, D.C. and across the region, and we are committed to developing a proton center to provide this safer clinical alternative to the populations that we serve, and also to bring our academic tradition, resources, and reputation to bear to help advance the development and evaluation of this technology.

Caring for Children at the Sibley Proton Therapy Center

Sibley is not traditionally a pediatric provider. The Johns Hopkins Children's Center, though, is a defining example of a pediatric provider with a history of delivering the best pediatric

care available, constantly discovering and developing the new treatments and devices, and training clinicians who provide care across the country and the world. Johns Hopkins has a long history of commitment to sub-specialized training, clinical care, research, and leadership in Pediatric Radiation Oncology, starting with Dr. Moody Wharam (CV included in Appendix 71E). By engaging multi-disciplinary programming, sub-specialized pediatric surgical oncologists, medical oncologists, radiation oncologists, radiologists, and pathologists collaborate in treatment planning for each pediatric cancer patient. These sub-specialized Oncology physicians participate in and in many cases lead Tumor Boards, National Pediatric Cancer Societies, and clinical trial research, ensuring that our pediatric patients and their families are provided the best comprehensive and individualized treatment plan, specific to each child's unique disease. The depth and breadth of resources in pediatric care at the Johns Hopkins Children's Center will be employed to support the development of Sibley as a premier pediatric provider in this area.

Proton therapy is not currently available in Washington, D.C., or in the Baltimore-Washington region. Refer to 51 In fact, though, there is an even broader need for services in Washington, D.C. where pediatric proton therapy and pediatric radiation therapy are combined into a comprehensive academic pediatric program with a mission of high quality clinical care, innovative pediatric radiation oncology research, and contemporary sub-specialized training in pediatric radiation oncology. Johns Hopkins has been the leading provider for more than thirty years in pediatric Radiation Oncology, and Johns Hopkins is committed to providing the region with dedicated full-time sub-specialty trained Pediatric Radiation Oncologists on faculty. The current JHM Pediatric Radiation Oncologist, Dr. Stephanie Terezakis (**CV included in Appendix 71F**) is an active leader in the multi-disciplinary programming described above. She is also an active leader in the Children's Oncology Group (COG), which is the world's largest pediatric oncology organization. The COG is an 8,000 expert member group from over 200 leading Children's hospitals, and it is exclusively devoted to pediatric cancer clinical research and care. As a leader in COG, she is the Principal Investigator for several national clinical trials, and she actively participates as a clinical trial reviewer.

Sibley, Johns Hopkins, and Children's National Medical Center are part of a strategic partnership that will result in the creation of a dedicated pediatric radiation oncology program as part of the Sibley Proton Project. As partners in the care of pediatric patients, Johns Hopkins and Children's National Medical Center will jointly recruit and employ a sub-specialty trained Pediatric Radiation Oncologist who will provide pediatric radiation oncology services on the campus of Sibley Hospital.[1] This partnership extends to the co-development and implementation of the Sibley Proton Therapy Center. This partnership will create the first complete comprehensive pediatric radiation oncology program in the region in which pediatric patients and their families will have direct access to the faculty expertise of Johns Hopkins and Children's National Medical Center, to sub-specialized multi-disciplinary care, and to comprehensive clinical trial research within the District of Columbia on the campus of Sibley Hospital. Pediatric patients and their families will no longer have to travel outside of the region to obtain comprehensive radiation oncology services that include life-preserving proton therapy.

[1] Sibley will file an application for a Certificate of Need, as required under the regulations, in order to be able to offer this needed service.

Sibley and The Johns Hopkins Department of Radiation Oncology have forged an agreement with All Children's Hospital, the Johns Hopkins Children's Hospital located in Florida, to formalize a referral program that will enable access to sub-specialized Pediatric Radiation Oncology care for its tertiary radiation therapy patients and its proton therapy-eligible patients at Sibley Hospital. This will provide patients from All Children's Hospital, which does not offer radiation therapy or proton therapy services, direct access to Johns Hopkins Pediatric Radiation Oncology services at Sibley. It will also facilitate participation in clinical research and fellowship training for All Children's clinicians. **(See Exhibit 74C for a copy of the signed Memorandum of Understanding)**

One of the most compelling reasons justifying the addition of a Proton Therapy Center to the Sibley campus is that it will enable us to provide the most contemporary care for children with cancer This specialized care will be available to all children who need it. Proton therapy for children will be facilitated across our health system and our partners. As the need for treatment in the pediatric population is demonstrated through our volume projections, the equivalent capacity of one entire treatment room, out of our proposed four treatment room system, will be devoted to treating children.

Research in Proton Therapy at Sibley

While there has been both clinical and biologic research with proton therapy in the United States over the past 20 years, the research has not kept pace with its clinical implementation. This proposal to develop the Sibley Proton Therapy Center is specifically formulated and dedicated to directly address this deficiency.

Clinical Trials: Every patient treated with proton therapy will be considered for enrollment in a clinical trial. In addition, the co-developed community based programs to educate Howard and other minority patients on the benefits of ethical clinical trials will greatly assist in expanding access to the newest, contemporary therapies for the minority community. The protocols that will be developed in the Sibley Proton Project will initially seek to answer questions of clinical efficacy with results that provide a data-driven understanding of whether proton therapy provides better outcomes than cheaper conventional therapies. Another important field of research will be to study and understand the effectiveness of combination therapies which use proton therapy in combination with radio sensitizers, chemotherapy, and conventional radiation protocols.

Biology: With the JHM expertise in laboratory-based biologic studies of cancer development pathways and cellular repair pathways, the Sibley Proton Project and JHM will have the opportunity to be the global leader in the study of the cellular response to proton therapy. This research will be critical to transform the clinical application of proton therapy, where in theory shorter courses of treatments using proton therapy may be comparatively more effective than longer conventional therapies, thus potentially changing the cost position of proton therapy to the cheaper clinical option. This research is part of the world class service the Sibley Project Proton seeks to create.

Technology Development: The major technologic development opportunities in proton therapy focus on verifying beam targeting prior to the application of every treatment and on controlling tumor motion. The Sibley Proton Project and JHM are well positioned to be the global leader in this development since JHM's faculty are the inventors of modern day Cone Beam CT imaging and Active Breathing Control technology. JHM's national leadership in

the development Radiation Therapy Safety Protocols will allow the Sibley Proton Project to ensure that Quality and Safety will be integral to all proton therapy programs.

Integration of the Sibley Proton Project with the Sidney Kimmel Comprehensive Cancer Center

The Sidney Kimmel Comprehensive Cancer Center ("**SKCCC**") is a National Cancer Institute-designated Comprehensive Cancer Center. The Department of Radiation Oncology and its faculty are an integral part of the SKCCC. The Vision of the SKCCC is to accelerate the transformation of cancer care by rapidly promoting the discovery of knowledge leading to the prevention and cure of human cancers. As the center of cancer research for Johns Hopkins, the SKCCC manages $197 million in cancer research funding, of which $84 million is grant funding from the National Cancer Institute. This funding supports cancer biology and cancer care research programs that are focused on new discoveries in cancer screening, cancer prevention, and cancer care. Cancer research at Johns Hopkins is a unique collaboration of multi-disciplinary teams across the Johns Hopkins University School of Medicine. The SKCCC has been successful in extending cancer research beyond the School of Medicine by collaborating with the Johns Hopkins University School of Public Health and the Johns Hopkins University Whiting School of Engineering. In total there are 275 basic science and physician scientists collaborating in laboratory research and clinical trial research. The SKCCC is currently managing 267 clinical trial studies, and enrolled 1,657 patients to clinical trials in 2011. Thus, 27% of the new cancer cases seen by the SKCCC were provided unique care protocols offered through these clinical trial research studies. Clinical cancer research is integral to the contemporary care that is provided by Johns Hopkins, and Johns Hopkins is committed to the discovery of new treatments that will increase the effectiveness and quality of care for patients with cancer. The Sibley Proton Program will extend SKCC to the District of Columbia.

The integration of the overall Sibley Oncology Program and the Sibley Proton Therapy Center with the SKCCC will provide significant opportunities to extend research to the District of Columbia. First, the Proton Center faculty will be able to directly collaborate with the multi-disciplinary SKCCC scientists to develop innovative laboratory and clinical trial research that will integrate the unique targeting of proton therapy with coordinated protocols, such as drug therapies, nano-particle targeting therapies, and tumor motion management protocols. Second, by coordinating the established JHU Department of Radiation Oncology Molecular Radiation Sciences Laboratory infrastructure with the research infrastructure planned for the Sibley Proton Therapy Center, the JHU Faculty will be able to conduct biological effectiveness research of proton therapy that is based on site specific cancers and high dose treatment planning methods. Third, leadership and collaborations in Medical Physics and Engineering research provides for unique opportunities in technology development. The Johns Hopkins University Department of Radiation Oncology Chief of Medical Physics, Dr. John Wong (**see CV in Appendix 71G**), has invented many of the most important technological advancements in radiation therapy, such as integration of cone beam CT on to linear accelerators and Active Breathing Coordination to help enhance accuracy of radiation to lung tumors. Dr. Wong will continue his discovery work with his partners in the School of Engineering to develop technology-based research programs at Sibley with the goal of improving the quality, safety, and effectiveness of care with Proton Therapy. Finally, the Sibley Proton Therapy Center will directly collaborate with the SKCCC to develop and implement an effective research mission that ensures that all proton therapy patients will be provided access clinical trials. The Sibley Proton Center will be governed by

the established infrastructure and protocols of the SKCCC to ensure the highest degree of quality and safety for clinical trial patients.

Education and Training Opportunities at the Sibley Proton Therapy Center

The development of multi-disciplinary clinics within Radiation Oncology has provided the opportunity to train residents and fellows from all specialties that treat cancer in the multi-disciplinary approach of cancer care. This unique approach to care provides all oncology trainees the opportunity to understand the underpinnings and rational for contemporary treatment protocols and the appropriate integration of surgical, chemotherapy, and radiation interventions. This same approach will be expanded to proton therapy for both JMH and Howard residents and fellows to ensure that all future leaders in oncology are trained on the application and value of proton therapy. These training and teaching efforts are described in further detail in the responses to questions 60, 61, and 62 below.

The Sibley Proton Project incorporates the Johns Hopkins Medicine System of Care

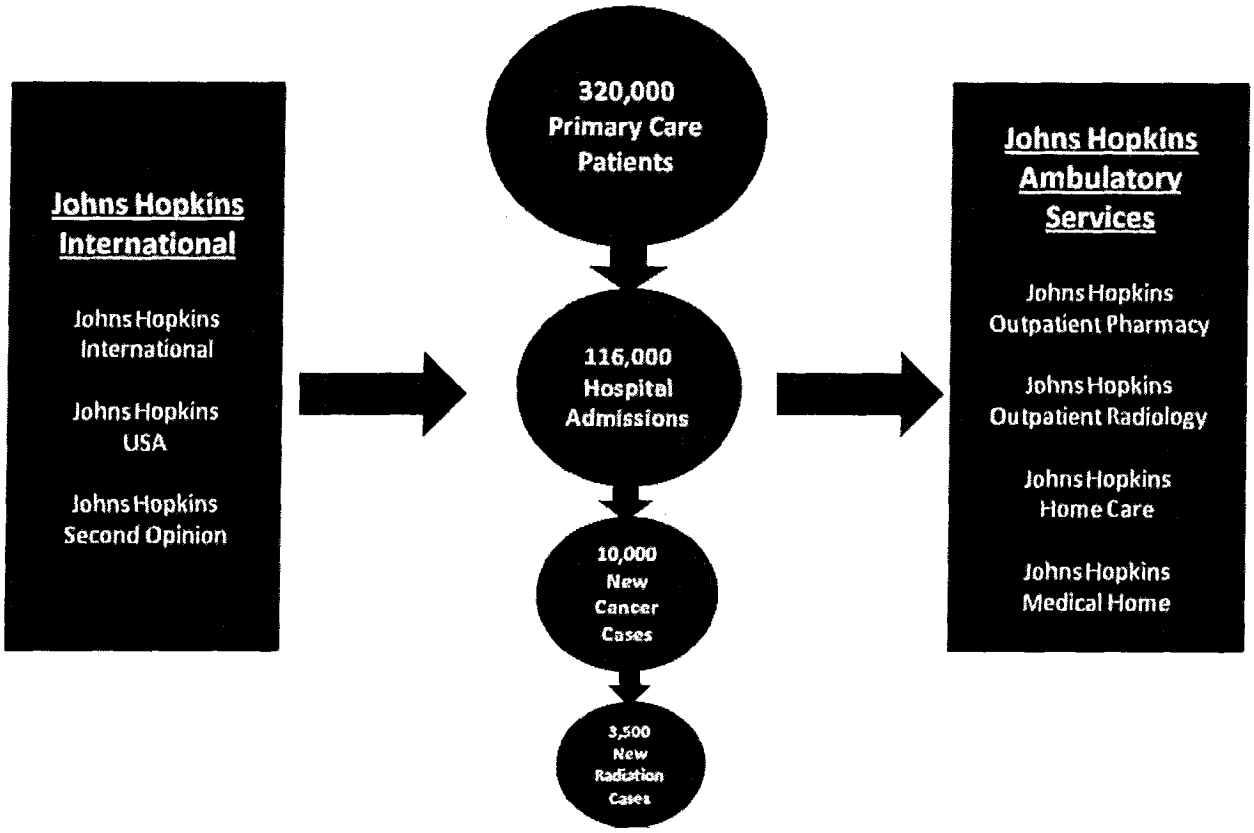
Sg2's report "Cancer Forecast: Managing the Change" **(Appendix 51F)** states that the success of a cancer program depends on its ability to connect with a system of care. With this in mind, the following healthcare trends are becoming more prevalent in the market.

- Care is being driven out of the inpatient hospital setting and into the outpatient setting.
- There is an emphasis to drive acute care service out of high cost tertiary care settings.
- Quality is an imperative throughout a patient's continuum of care.

It will take a well-integrated system of cancer care to respond to these healthcare trends and succeed as a comprehensive cancer program. The Sibley Proton Project is part of the Johns Hopkins System of Care which makes possible the integration that is consistent with the current day trends. Figure 2 provides the picture of the integrated system that is the Sibley Proton Project.

Figure 2:

The Sibley Proton Project brings to the District of Columbia the Johns Hopkins System of Care



Sibley, a member of JHHS, is part of Johns Hopkins Medicine, which is a unique system of care that is well positioned to succeed in providing comprehensive, academic-based cancer care, to include proton therapy. The JHM depicted in Figure 2 above and described below, of which Sibley is a part, is well-positioned to provide the integrated system of cancer care to help make a successful proton therapy program, with the extensive resources and talent base to manage the highly specialized use of the technology and the high capital and operational costs:

Primary Care: Johns Hopkins Community Physicians ("**JHCP**") is the Division of Johns Hopkins Medicine that manages primary care for the population in Washington, D.C. and Maryland JHCP has clinical operations in 32 locations across the District of Columbia, and Maryland and the JHCP physicians manage care for 320,000 adult and pediatric patients, resulting in approximately 800,000 visits annually.

Community Hospitals: Through Johns Hopkins Health System, Johns Hopkins manages acute and tertiary care at Sibley Memorial Hospital, Suburban Hospital, Howard County General Hospital, and All Children's Hospital in Florida. The Johns

Hopkins Community hospitals provide care for 49,000 admissions and 540,000 outpatient visits annually.

Academic Medical Centers: The Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center are the Academic Medical centers that provide acute, tertiary, and quaternary care in an academic setting, combining clinical care, research, and teaching. The Johns Hopkins Academic Medical Centers provide care for 67,000 admissions and 625,000 outpatient visits annually.

Cancer Care: The flagship comprehensive cancer program for Johns Hopkins is the Sidney Kimmel Comprehensive Cancer Center located at the Johns Hopkins Hospital, where 6,800 new cancer cases are managed annually. Oncology services are also provided at Johns Hopkins Bayview Medical Center, Howard County General Hospital, Suburban Hospital and Sibley Hospital, and these Johns Hopkins cancer programs manage 3,300 new cancer cases annually. Of the 10,100 cancer cases managed by Johns Hopkins, 3,500 of these new cancer cases receive radiation therapy services at a Johns Hopkins Radiation Oncology site.

This system of care is supported by Johns Hopkins International and Johns Hopkins USA, who assist in providing access to patients from outside of our primary regional service area. These out-of-region patients seek the expert clinical care, innovative clinical trials, and unique tertiary and quaternary services provided by Johns Hopkins clinical care teams. This Johns Hopkins system of care also provides patients access to ambulatory care at Johns Hopkins through outpatient radiology, home care, and pharmacy services. Finally, this total system of care is informed and guided by Johns Hopkins HealthCare, the Johns Hopkins managed care organization, which manages the healthcare of more than 250,000 members.

Johns Hopkins Medicine and Sibley Memorial Hospital are committed to improving the access to and quality of care across all of its entities. Johns Hopkins and Sibley have invested in a multi-year strategy to incorporate a single electronic medical record across the clinical care system. This provides a single repository for clinical records for each patient and a single patient number that will be shared by all entities. This investment will streamline access across Johns Hopkins and will improve the quality and timeliness of clinical documentation for all care providers across Johns Hopkins. Sibley, as part of the Community Division of Johns Hopkins will be the first Johns Hopkins Hospital, along with sister hospital, Howard County General Hospital, to implement the Epic System, which is scheduled for Summer of 2013. As mentioned above, there is also an EMR product for private community based physicians which will allow community physicians to utilize this same system. Epic currently covers approximately 40% of all patients in the United States. This will enable patients treated within the Johns Hopkins System to seamlessly transfer back to home providers whether it is as a patient in the Sibley Proton Center or due to a visit in Sibley's Emergency Department.

Together, these resources make the Sibley Proton Therapy Center a unique capability in the District of Columbia, which will be the singular proton therapy service that will support the patient population of the entire Johns Hopkins Health System and community. The Sibley Proton Therapy Radiation Oncologist will work with multi-disciplinary oncology teams across the Johns Hopkins Health System to ensure that proton therapy is an integral treatment modality in the care of our cancer patients. With the integration of a singular electronic medical record, patient referrals to the Sibley Proton Therapy Center will be streamlined and

the communication of clinical information will be directly accessible in real time to all Johns Hopkins providers. In addition, a patient's care following proton therapy treatment will be efficiently transferred back to the primary care team. The Johns Hopkins System of Care is well positioned to ensure the success of the Johns Hopkins comprehensive cancer programming, and it is well positioned to provide our health care community with the most effective and efficient access to comprehensive clinical care, clinical trial research, and cancer education and training.

Description of the Sibley Proton Therapy Center Facility

The Sibley Proton Therapy Center is planned to be a 44,000 square foot facility that includes the following technology, clinical services, research services, and administrative services.

Technology: The facility will house a 230 MeV cyclotron proton accelerator. The proton therapy beam line will extend from the accelerator and will service 4 treatment rooms. Three of the treatment rooms will each utilize a 360 degree rotational gantry to deliver the proton beam therapy to the patient. These will be the primary clinical treatment rooms. The fourth treatment room will utilize a fixed beam delivery system for the proton beam, and this treatment room will have a split use of research and clinical treatments. The proton therapy system will have an integrated information technology infrastructure that controls the communication and quality assurance of the proton beam. Proton therapy treatment planning will be conducted in the facility, and the Treatment Planning System (TPS) will be directly integrated with the proton therapy equipment IT infrastructure. Likewise, the operating information system (OIS) of the Proton Therapy Center will be housed in the facility and will be integrated with the proton therapy equipment and planning information systems. Finally, the proton therapy center will include Computed Tomography and Magnetic Resonance Simulation equipment which are required for proton therapy treatment planning. These Simulation systems will be directly integrated with the OIS and the TPS of the facility.

Clinical Services: The facility will house comprehensive consultation clinic space that will be utilized for proton therapy consultation, follow-up care, examination services, nursing care, and patient education. There will be dedicated pediatric consultation and waiting room space that will be customized to the special needs of our pediatric patients and their families. Within the proton treatment area of the facility, there will be a dedicated pediatric preparation and recovery area for our pediatric patients who will require anesthesia when receiving treatment. We anticipate that 30-40% of our pediatric patients will require anesthesia. These clinical services will be supported by a team of dedicated nurses and advanced practice professionals. Medical Physics infrastructure will be located in the facility to ensure direct oversight and quality assurance of the equipment and treatment delivery. Finally, the Medical Dosimetry infrastructure will be located in the facility as well to ensure efficient treatment planning collaborations with the Radiation Oncologists, Medical Physicists, Radiation Therapists, and Dosimetrists.

Clinical Trial Research Services: The facility will include the resources to support the robust clinical trial services that are being planned for proton therapy patients. This includes adequate space to support research nurses and clinical trial data

coordinators to ensure that the appropriate evaluation, scheduling, data collection, and quality assurance services are immediately available for patients and the Radiation Oncologists.

Administrative Services: Comprehensive services will be provided in the facility to address the administrative needs of our patients. The facility will be support by Patient Service Coordinators who will assist patients with directions, scheduling, and registration, and they will act as advocates for our patients who are seeking additional information about their care. Financial counselors will be located in the facility to assist patients with questions regarding insurance, policy coverage, and other financial aspects of their care. Finally, there will be dedicated conference room space to facilitate multi-disciplinary conferences and tumor boards, and there will be dedicated patient education and resident teaching resources.

Strategic Partnerships

Sibley and Johns Hopkins are committed to developing and maintaining a robust portfolio of innovative research and proton therapy-based programmatic education and training of clinical oncology providers, and we are implementing a strategy to deliver these commitments by formalizing strategic, mission-based partnerships in proton therapy.[2] See Memos of Understanding and Letters of Intent in Appendix 74

a. *Children's National Medical Center ("**CNMC**")* – Johns Hopkins and Sibley will partner with CNMC to develop a comprehensive pediatric radiation oncology program at Sibley. Sibley CNMC and Johns Hopkins will develop a multi-disciplinary pediatric oncology program that will span campuses and provide the District of Columbia's pediatric oncology patients with access to world class oncology providers, to coordinated pediatric oncology programming under the leadership of specialty trained pediatric oncologists, and to collaborative clinical trials. CNMC will partner with Sibley to bring proton therapy to the pediatric cancer community in Washington, D.C., the Sibley Proton Project's Primary Services Area and Regional Service Area so that patients and their families will have local access to proton therapy and not have to be displaced from home for weeks at a time while seeking proton therapy care outside of the region.

b. *Howard University Hospital ("**HUH**")* – Johns Hopkins has had a long standing partnership in Oncology research and training with Howard University. Johns Hopkins, Sibley, and HUH are formalizing a partnership that is founded on this established research relationship and are extending it to include proton therapy. As partners in proton therapy, Sibley Johns Hopkins and HUH will work to develop collaborative programming that provides proton therapy access to HUH cancer patients, that grows current collaborative research to include proton therapy, and that develops training opportunities for Oncologists, Medical Physicists, other clinical professional and undergraduate and graduate students.

c. *All Children's Hospital* – All Children's Hospital is a John Hopkins pediatric hospital located in Tampa, Florida. All Children's Hospital does not have access to proton

[2] The list below depicts our current conversations with partners, but it is not exclusive. We are eager to create innovative partnerships that will help ensure the greatest benefit from this project for all.

therapy in Tampa, and patients must be referred to out of area proton therapy centers such as Massachusetts General Hospital, MD Anderson, and University of Florida. All Children's, Sibley, and The Johns Hopkins University School of Medicine have executed a Memorandum of Understanding to develop a Collaborative Program which will provide access to Johns Hopkins proton therapy and tertiary radiation therapy at Sibley through the collaborative multidisciplinary management of cancer patients, and which will establish collaborative research and training programs in pediatric oncology.

d. *American University (**"AU"**)* – Similarly, AU, Johns Hopkins, and Sibley are exploring a partnership that would provide opportunities in Medical Physics research and training for AU undergraduate and graduate physics students at Sibley.

e. *Walter Reed National Military Medical Center* ("**WRNMMC**") *and The National Cancer Institute* ("**NCI**") – WRNMMC, NCI, and Johns Hopkins have initiated discussions to explore opportunities to develop clinical trial research and laboratory research collaborations in the study of proton therapy at Johns Hopkins and Carbon Therapy at the proposed Carbon Therapy Center at WRNMMC. WRNMMC, NCI, and Johns Hopkins have initiated discussions to explore opportunities to develop a collaborative Medical Physics clinical and research program in proton therapy at Johns Hopkins, and Carbon therapy at WRNMMC.

f. *WellSpan Health* – WellSpan Health is an integrated health system that includes cancer programming at WellSpan York Hospital and WellSpan Gettysburg Hospital. The WellSpan cancer program provides clinical services to 2,400 new cancer patients annually. WellSpan and Johns Hopkins have had a long-term partnership that includes The Johns Hopkins Hospital as the primary tertiary referral site for WellSpan's cancer patients. Sibley, Johns Hopkins, and WellSpan are formalizing partnership planning that will expand the current relationship to include the Sibley Proton Therapy Center as a referral site for WellSpan's proton therapy patients.

g. *Sumitomo Heavy Industries* ("**SHI**")– Sibley, Johns Hopkins, and SHI are formalizing a partnership in proton therapy that includes the following:

- Purchase and sale of a state of the art proton therapy system that includes 4 treatment rooms, 3 rotational gantries and a fixed beam research room.
- Develop the Sibley Proton Therapy Center as SHI's global reference site.
- Co-Develop technology research programming at Sibley.
- Develop the Sibley Proton Therapy Center as a global training for SHI customers and clinical partners.

h. *Elekta* – Johns Hopkins and Elekta have a long standing partnership in Radiation Oncology which includes purchase transactions of equipment and software, technological research co-development, and customer reference site access. Sibley, Johns Hopkins, and Elekta are formalizing an extension of this partnership to include collaborative development of proton therapy operating system integration, proton therapy treatment planning, and proton therapy reference site access.

In summary, Sibley and Johns Hopkins are actively extending existing relationships as well as creating new partnerships that encompass leaders in the field of cancer care focused on the advancement of clinical care, research, and education in proton therapy. The intent of these partnerships is to substantively advance the knowledge in and appropriate clinical use of proton therapy through development of the Sibley Proton Therapy Center. These unique collaborations will directly benefit cancer patients in the Washington, D.C. and in the PSA and RSA by providing access to full a spectrum proton therapy program that is predicated on a programmatic approach with clinical and research partners that advances the development of the finest proton therapy center in the United States.

Conclusion

1. The Sibley Proton Project has the resources to build and develop a Proton Center that will excel in all three domains of the Johns Hopkins Tripartite Mission: clinical care, training, and research.

2. The Sibley Proton Project includes sufficient capacity to care for referred pediatric cases, specifically-indicated adult tumors (head, neck, spine, etc.), and patients in clinical trials, as well as to allow access to the equipment for training and research.

3. Pediatric residents of Washington, D.C., will have access to comprehensive, coordinated pediatric radiation oncology, including this transformative therapy that is Proton therapy when indicated.

4. The Sibley Proton Project partnership with Children's National Medical Center, among other institutions, will enable us to reach children in need with this therapy. We estimate roughly 50 referrals from Children's National Medical Center. Over 50% of the patients at Children's are insured by Medicaid, indicating that their families are low-income. It is fair to assume that most of the children referred and insured by Medicaid would be challenged if required to seek this treatment, needed over the course of 30-45 days, in a city hundreds of miles away.

5. The Sibley Proton Project partnership with Howard University will facilitate patient referral and will also enable clinicians and trainees to gain expertise on this new equipment and with this treatment modality.

6. Sibley, Johns Hopkins, Children's National Medical Center, and Howard University Hospital, all who have an established history of providing World-Class Oncology Leadership and Oncology Care to the patients of Washington, D.C., of the Sibley Project's Primary and Regional Service Area, and of Out of Region Domestic and International populations, are committed and have the resources to build a world-class Proton Therapy Center in the world-class city of Washington, D.C.

49. Explain in detail how the project is consistent or inconsistent with the Comprehensive Health Plan

Response:
The Sibley Proton Project is consistent with the District of Columbia State Health Plan and the District of Columbia Healthy People 2010 Biennial Implementation Plan because the

Sibley Proton Project will positively impact the high rates of cancer in the District of Columbia.

According to the District of Columbia State Health Plan ("State Plan") cancer is one of the Top 10 Causes of Death in the District of Columbia. Indeed, cancer is the second leading cause of death and the residents of the District of Columbia have one of the highest rates of cancer in the United States. Consequently, cancer is a leading health issue affecting the health status of the District of Columbia residents and has a major effect on decreased life expectancy rate. According to the District of Columbia State Plan (see State Plan at page V),

> "An analysis of leading morbidities presents an opportunity to allocate health care resources for prevention and treatment to areas where these resources are most needed and where they are most likely to make a difference."

The Sibley Proton Project will make a difference to the District's children and adults as it will create cancer treatment options that are currently unavailable. Moreover the treatment options created by the Sibley Proton Project are healthier alternatives to the existing radiation therapies that are available to the residents of the District.

In addition, cancer is one of the leading causes of death in which the disparities between white and black are almost double. According to the State Plan, health disparities exist when there is "inequity in available opportunities to access high quality and affordable health care by varying racial, ethics and social economic groups." See State Plan at page VIII. According to Healthy People 2010 Plan,

> "the poor and the medically underserved sub-populations, mostly African Americans and other minorities, lack access to cancer care services. Further, the inequitable distribution of cancer care plays a major role in the city's high mortality rates. The racial/ethnic disparity with regard to cancer prevention and treatment (that is, screening, early detection, survivorship, palliative and en care) is significantly substantial."

Healthly People 2010 Plan, at page 70.

The Sibley Proton Project will expand cancer treatment options for the children and adult residents of the District of Columbia. In addition, together with one of Sibley's Proton Project partners – Howard University – the Sibley Proton Therapy Center will develop a community-based program to educate the Howard patient community on the benefits of ethical clinical trials in oncology and how clinical trials can provide access to the newest, contemporary therapies. That program will be designed to differentiate the proton clinical trials from clinical trials that occurred in the past, such as at Tuskegee, which have given clinical trials a bad name in many communities. Consequently, the Sibley Proton Project will not only provide unprecedented cancer treatment options for Washington, D.C. residents, but it will also provide an effective approach to address health disparities in cancer treatment both through education programs and new treatment options.

In summary, the Sibley Proton Project will positively impact the leading cause of death and a health condition with a high rate of health disparities, making it consistent with the planning framework of the State Health Plan as well as Health People 2010.

Availability
Currently there are 10 proton centers in operation in the United States. (See map at Appendix 22B.) There are another 21 centers either under development, planned, or announced. The nearest proton therapy center to Washington, D.C. that is operating is in Philadelphia, nearly 150 miles away. The usual treatment course for proton therapy is 30-45 treatments on consecutive days. Having to travel more than a couple of hours each way, every day, is a barrier to care unless a patient and his or her family can afford to relocate near the proton therapy center for the course of the treatment. Simply put, this project will result in proton therapy being available, while it currently is not available, to the large proportion of the population of Washington, D.C. due to lack of resources to relocate.

Accessibility
The high cost of establishing a proton therapy is one of the reasons that there are currently only ten centers in operation in the United States. Sibley Memorial Hospital and Johns Hopkins Medicine consider proton therapy to be a mission-centric imperative for the care of the cancer population in Washington, D.C. and across the region, and we are committed to developing a proton center to provide this safer clinical alternative to the populations that we serve, and also to bring our academic tradition, resources, and reputation to bear to help advance the development and evaluation of this technology.

Our charity care policy, to which both Sibley and Johns Hopkins Medicine are both very committed, will of course apply to this service. Through our partnership with Children's National Medical Center ("CNMC"), we are making a particular commitment to accessibility for the children of D.C. and the larger catchment area typically served by CNMC. The financial projections for this project include a payer mix reflective of this commitment. The payer mix typically seen at Sibley has a relatively low percentage of combined Medicaid products, and also a low percentage of self-pay/charity care designations. We have shifted this ratio significantly in our financial projections for this project, in anticipation of serving a larger number of CNMC referrals and referrals from Howard University. The proportion of patients with Medicaid coverage is over 50 percent at both of these partner hospitals.

For the recently opened radiation center at Sibley, hours of service are 7:00 a.m. to 5:00 p.m., with flexibility to extend to 7:00 p.m. At Massachusetts General Hospital, the proton therapy center is open 10 hours per day. The Sibley Proton Therapy Center will be open for patients for an estimated 13 hours per day once in full operation. These hours will be adjusted to accommodate additional patient volume, as demand dictates.

The Proton Therapy Center will be fully ADA compliant and accessible by car either directly from the garage or at a convenient drop-off location at the front entrance of the building. In addition, numerous bus lines and shuttle bus service is available to patients and staff to and from Friendship Heights Metro Station, running 6:00 a.m. – 6:00 p.m., Monday through Friday. Also see response to question 66 for further detail.

Quality
The quality standards, policies and procedures in place to ensure they are met, for Radiation Oncology currently and for the Proton Therapy Center when implemented are described thoroughly in response to question 71. In short, the Johns Hopkins Department of Radiation Oncology is a world leader in the area of radiation safety and quality assurance. Sibley, Johns Hopkins University, and the Johns Hopkins Health System have been actively collaborating to integrate their Radiation Oncology programs. The integration was strategically implemented with the goals of enhancing the quality of the Sibley Radiation Oncology program by standardizing the radiation equipment and information systems between Sibley and John Hopkins, by standardizing the patient information management systems between Sibley and Johns Hopkins, thus enhancing communication and collaboration on multidisciplinary patient care, by enhancing access to new and innovative clinical trials, including advanced non-radiation emitting image guidance and motion management, and by standardizing Radiation Oncology specific quality and safety programs between Sibley and Johns Hopkins. The robust quality and safety infrastructure of Johns Hopkins, already being leveraged to strengthen the quality and safety in Radiation Oncology at Sibley, will be brought to the Proton Therapy project, ensuring the highest standards for quality and safety.

Continuity
Due to the highly specialized nature and limited, regional availability of this service, we expect a large number of referrals from a wide range of hospitals and providers. Maintaining continuity of care as much as possible will be a high priority. Every effort will be made to ensure communication and collaboration with referring entities. A benefit of practicing within a system includes having a high degree of coordinated care (systems, human resources and processes). The new EMR being implemented within the Johns Hopkins system, referenced further in this document, will facilitate this for our system hospitals. In addition, the articulated partnerships with Children's National Medical Center and Howard University will include a plan for streamlining the handoffs for our mutual patients and ensuring excellent provider-to-provider communication. Regardless of referral source, however, effective transfers with excellent communication are a high priority. Referrals out to other providers, when necessary, will be made based on quality, value, and patient preference.

Acceptability
Sibley and Johns Hopkins are experienced healthcare providers and are committed to transforming healthcare to achieve the highest value and best experience for our patients, and to bring the latest innovations and discoveries to bear for the benefit of our patients. Each expansion and every new program is driven by the goal to provide exceptional care to the people and communities served. Representatives of the Advisory Neighborhood Commission have been advised of this proposed project see Appendix 73. As we move forward, they will continue to be integral to our planning and implementation process. Sibley policies related to patients' rights and grievance procedures will apply to proton therapy services just as they do to all other services offered. These are further discussed in the response to question 68 and associated appendices.

Cost
At this time, proton therapy is an expensive service to develop. It can be life-saving and life-preserving, though. Insufficient information exists to fully assess the impact of proton therapy on overall health care costs. There are cases, particularly in the area of head, neck

and spine tumors, lung tumors, and pediatric tumors, where the added expense of proton therapy would be offset by the avoidance of costs associated with collateral tissue damage and other debilitating side effects, especially in pediatric patients. Additionally, for this project, one treatment room will be devoted to research. It is only through the execution of carefully designed clinical trials, including rigorous analysis of outcomes and total costs, that we can fully understand the true cost of this treatment compared to the alternatives. Through the approval and implementation of this project, that information will be attained more quickly, and with the rigor and expertise of Johns Hopkins and the Sibley Proton Center behind it.

In Conclusion

The Sibley Proton Project is consistent with both the State Health Plan and the Healthy People 2010 Plan, because it provides unprecedented access to cancer treatment that is focused on impacting the high rates of cancer experienced by the residents of Washington, D.C..

50. Does your facility have a long range plan? If so, explain the relationship of this project to the plan. If there is no long range plan, explain how the project relates to the overall goals of the facility.

Response:
Sibley's mission is to provide quality health services and facilities for the community, to promote wellness, to relieve suffering and restore health as swiftly, safely and humanely as can be done consistent with the best service we can give at the highest value for all concerned.

At this time, Sibley Memorial Hospital has plans to complete the campus master plan that includes new facilities, and renovations approved in CON 10-3-1. This CON includes construction of a replacement patient pavilion and cancer center as well as an expanded Emergency Department. Sibley's long term plan also includes a continued integration Johns Hopkins Medicine, the transaction with which was completed in November of 2010.

Within the Definitive Agreement, the document which governs the relationship between Sibley and Johns Hopkins, it is clearly stated that oncology will be an integral area of service line support and integration. This service is the area in which the most progress has been made in moving toward clinical, research and educational integration.

51. Discuss the need that the population to be served has for the services proposed to be offered or expanded. Explain how you reached the conclusion that there is unmet need. Include an analysis of the area and population to be served, the present and future utilization patterns of the proposed facility and service(s), and the impact of the proposal, if implemented, on the utilization of existing facilities and services in your area. Use the methodology (if any) specified in the Comprehensive Health Plan. Demonstration of an unmet need is essential to approval of an application for a CON.

Response:
The principles that guide the practice of Radiation Oncology ("Principles") as a tool for treating cancer are as follows:

1. To deliver clinically effective radiation dose to the tumor
2. To protect healthy tissue

These Principles apply to all forms of conventional radiation therapy used as a therapeutic intervention for pediatric and adult cancer patients. The Principles guide the continuous development of radiation delivery technology, which to date has included robotic linear accelerators, real time CT imaging, and targeting techniques that are accurate within a few millimeters. Even with these advances, though, the exposure of healthy tissue to radiation dose cannot be avoided, thus limiting the positive clinical impact of conventional radiation therapy.

The Unavoidable Damaging Effects of Conventional Radiation Therapy

Conventional Radiation Therapy delivers a dose of radiation through streams of energy called photons. Photons are created when electrons interact with one another, thus resulting in a release of energy. Radiation Oncology clinicians are able to control the volume of electron interactions and the direction of the interactions so that the release of energy creates a photon beam that travels through the patient and delivers radiation dose to all the tissue (healthy and cancerous) with which it interacts. A Radiation Oncologist will use multiple beams that intersect at the site of the tumor in order to deliver the maximum dose to the tumor and minimize dose to each path of healthy tissue. Even though the exposure of healthy tissue to radiation is minimized, damage to healthy tissue is inevitable, and depending on the type of patient and the location of the tumor, the damage may have no clinical impact or it could have clinically significant impact. Patients that have the highest risk of clinically significant impact are all pediatric patients, and adult patients that are being treated at sites such as the brain, the spine, the neck, and the lung. An example of this can be seen in Figure 1, which shows the radiation dosing plan using traditional photon radiation for a pediatric patient with an eye tumor.

The Figure 1 image shows a colored band depicting the path of radiation that is planned for the treatment of this patient's eye tumor. Deep red colors indicate high amounts of radiation dose and blue colors represent lower amounts of radiation dose. For this pediatric patient, the eye receives the highest dose, but because conventional radiation travels through the body, it is unavoidable that a significant amount of healthy tissue also receives radiation dose. The following describes the risks to the patient due to the unavoidable dose to healthy tissue and the long term problems that could manifest.

The Pituitary Gland: The pituitary gland is responsible for the creation of various hormones in the body. The exposure to radiation for this pediatric patient could cause Pituitary dysfunction. Some of the long term effects on the patient include:

- Lack of growth hormone causing issues of growth development;
- Reproductive deficiencies; and

- Irreversible dependence on hormone replacement through steroid therapies.

The Facial Bone: The exposure to radiation could cause a lack of growth in these bones causing issues with facial development.

The Brain: In this plan, a large portion of healthy brain tissue is exposed to the path of conventional radiation. This toxicity can cause significant issues with cognitive delay and social adjustment, which can result in an inability to effectively learn and succeed in higher education and an inability to develop a successful career. The long term patient impact is the inability to have a high quality, functional life. This long term impact often causes collateral medical issues that have to be managed, such as depression.

The Retina: The retina of the healthy eye is unavoidably exposed to the conventional radiation in this example. This exposure creates a significant risk of developing retinopathy, which can lead to blurry vision and potential unnecessary loss in vision. There is also a significant risk that the healthy eye will experience chronic dryness requiring long term symptom management.

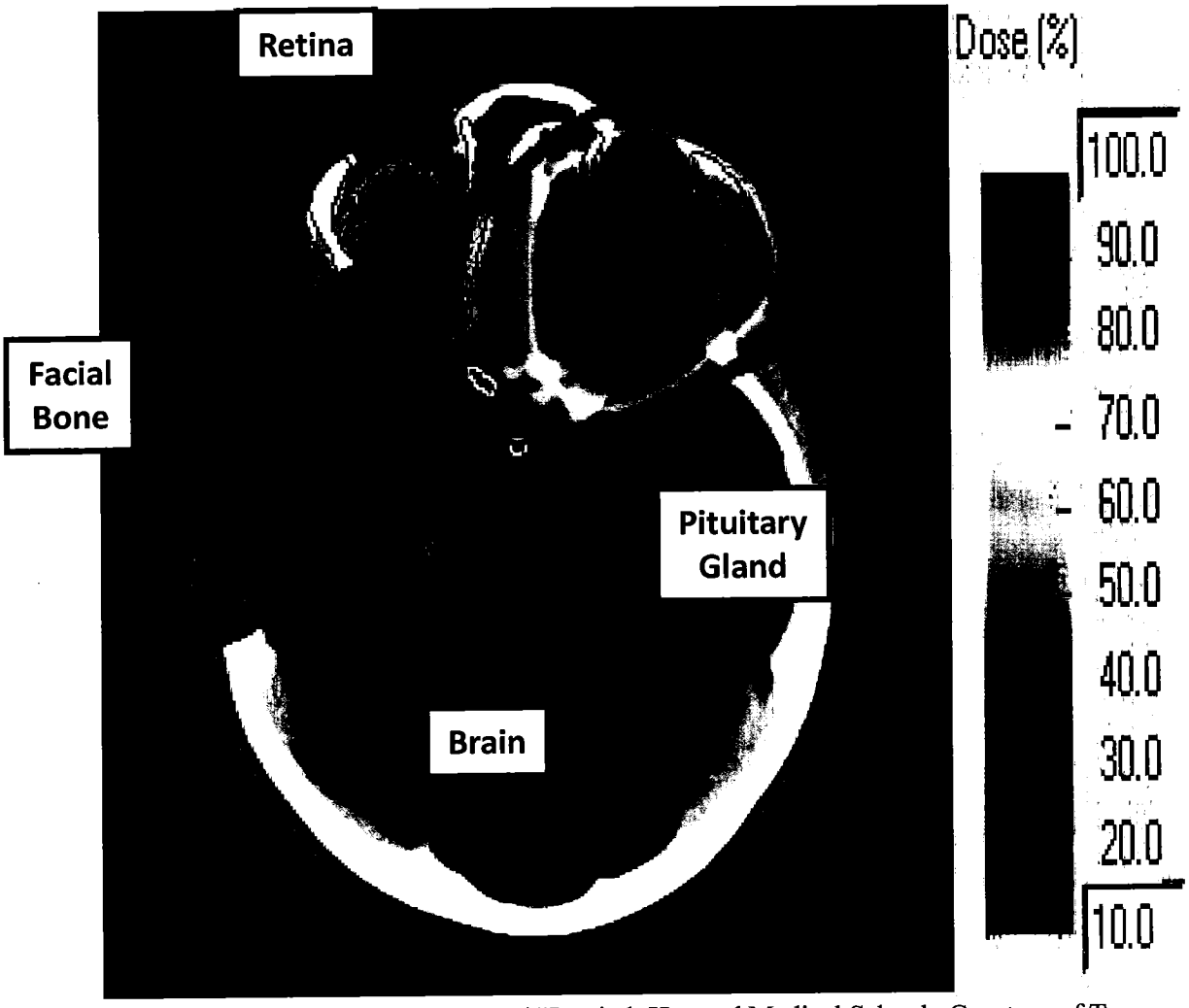
The Vasculature: Though the vasculature cannot be seen in this image, the blood vessels in the exposed brain create a significant risk for the patient because the radiation toxicity can cause irreversible vascular abnormalities that are prone to bleeding. If this occurs, the patient will have a higher risk of stroke.

Secondary Malignancy: Also not depicted in Figure 1, the patient is exposed to the risk of developing a secondary malignancy due to the exposure of healthy tissue to conventional radiation dose.

When faced with the choice between defeating cancer or succumbing to it, the risks to healthy tissue associated with radiation exposure summarized above become a necessary evil of survival. The aim of the Sibley Proton Project's clinical program and research and development is focused on minimizing and hopefully eliminating the risks and collateral damage described above, making the choice of treatment easier and safer, and the prospects of a longer life and a higher quality of life because of less damage greater.

Figure 1:

Orbital Sarcoma Treated with Conventional Photon Therapy



Note: Images are from Massachusetts General Hospital; Harvard Medical School. Courtesy of T. Yock, N. Tarbell, and J. Adams.

Proton Therapy: the Safer Therapeutic Alternative

Over the past forty years, more than 50,000 patients globally have been treated with an alternative to conventional radiation therapy, called proton therapy. As described above, conventional radiation therapy relies on electrons to create photon beams of radiation that travel through the patient. Proton therapy creates a beam of protons that is used to target and kill cancer cells. Proton Therapy has a significant advantage over photon therapy. ***The radiation dose of the proton beam can be controlled "extremely precisely," targeting nearly all the radiation to the cancer cells and minimally exposing healthy tissue.*** Unlike conventional radiation photon beams, Proton Therapy beams do not travel through the patient. They can be stopped at the tumor. Figure 2 shows the images of the proton

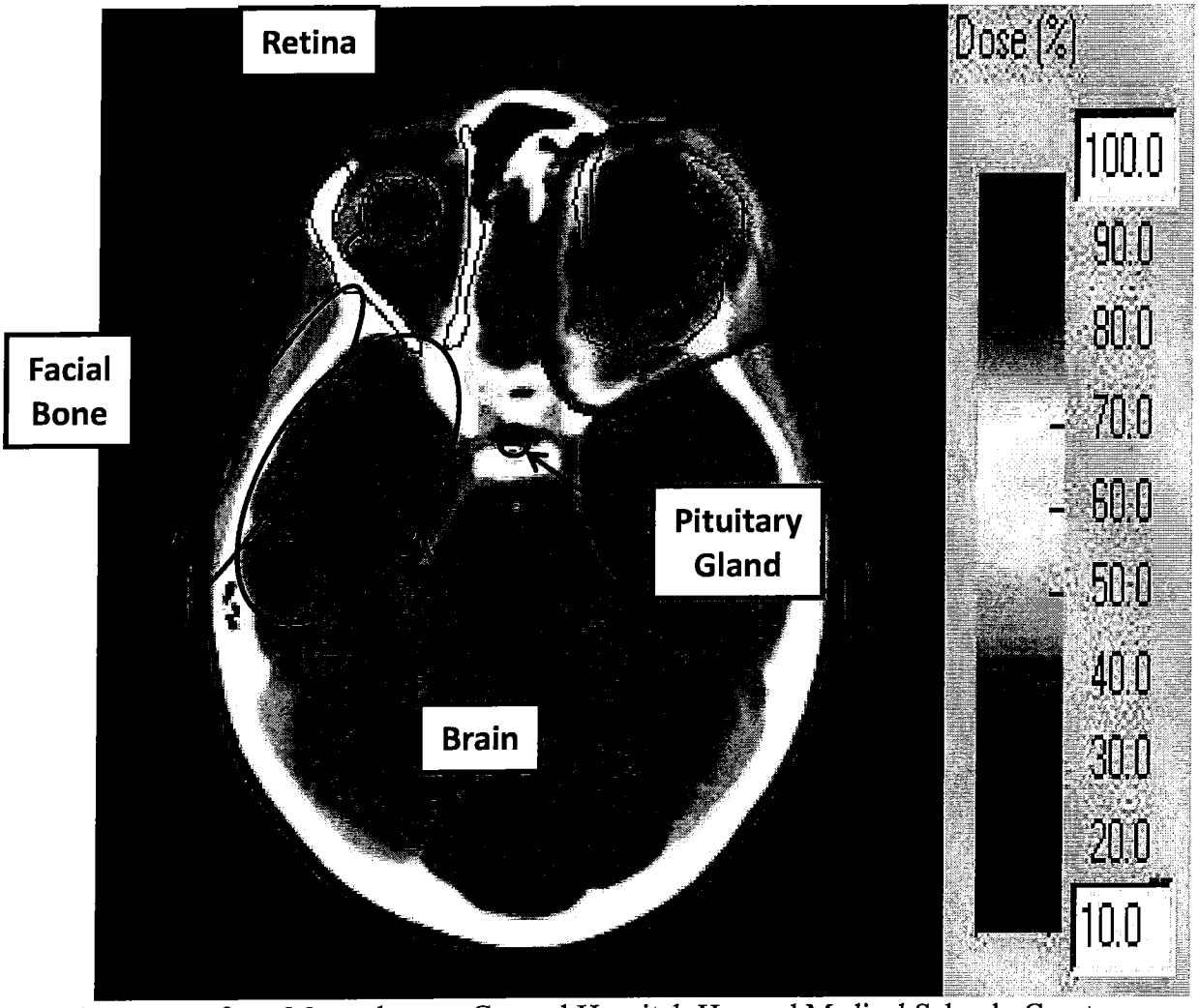
beam radiation treatment for the same pediatric patient discussed in Figure 1. The advantages of proton therapy could not be more explicit:

- Nearly all of the proton radiation dose is deposited at the site of the tumor, resulting in a higher dose of radiation to the tumor and a dose that is significantly more conformal to the tumor;
- There is no exit dose. Unlike the conventional radiation path discussed above, the proton therapy beam stops at the site of the tumor. There is no exposure to the Pituitary Gland, to the healthy eye or to the healthy facial bone. The large portion of the healthy brain receives no radiation dose, which also means no exposure to the vasculature in the brain and less risk of secondary malignancy; and
- The risks and long term effects on the pediatric patient as discussed in Figure 1 are greatly minimized if not completely eliminated. This patient has a much greater likelihood of leading a long, high quality life, free of radiation toxicity side effects.

This patient example, provided by Massachusetts General Hospital, illustrates concretely the value of this safer, higher quality alternative for cancer patients. Providers and patients are challenged, however, to achieve optimal treatment because of a lack access to Proton Therapy. There are only ten proton centers in operation in the United States. Sibley Memorial Hospital, Johns Hopkins, Children's National Medical Center and Howard University consider Proton Therapy to be a mission-centric imperative for the care of the cancer population in Washington, D.C. and in the Primary and Regional Service Areas. As a team, we are committed to developing the Sibley Proton Therapy Center to provide this safer clinical alternative and to advance the development of the technology and the discovery of new potential proton therapies.

Figure 2:

Orbital Sarcoma Treated with Proton Therapy



Note: Images are from Massachusetts General Hospital; Harvard Medical School. Courtesy of T. Yock, N. Tarbell, and J. Adams.

The Sibley Proton Project Market Need Analysis

The Sibley Proton Project proposes to develop a four treatment room proton therapy center with a mission to provide high quality clinical care, conduct innovative research and discovery, and advance contemporary oncologic education and training. To accomplish this mission, the Sibley Proton Therapy Center will have three treatment rooms dedicated to clinical treatment—one for pediatric cancer patients and two for adult cancer patients—and one treatment room primarily utilized for innovative treatments on protocol, research, discovery, and development. Contemporary oncologic training will be embedded in all clinical and research programs.

The Sibley Proton Therapy Center will serve three distinct markets: the Regional Service Area (RSA), the Other Domestic Service Area (ODSA), and the International Service Area (ISA). The definition of the Regional Service Area (RSA) for the Sibley Proton Project is informed by the study of the service areas used by existing proton therapy centers and proton therapy centers that are under development.

- *Provision Center for Proton Therapy, Knoxville, TN* – In a successful Certificate of Need application in Knoxville, Tennessee, the applicant stated that Industry Interviews and CON research indicates that the primary service area for a proton center includes a region with a radius of 100 to 200 miles from the proton center. The applicant further stated that significant volume would come from other U.S. regions and foreign countries. In this application the primary service area represents a 150 mile radius from Knoxville, which includes a population of 4 million people and is expected to generate 55% of patient volume for their three treatment room facility. Their total market includes a broader regional area, inclusive of the RSA, which is approximately a 250 mile radius from Knoxville and includes a population of 22 million people. The Knoxville project received unanimous approval from the Tennessee Health Services and Development Agency in 2010. (See **Appendix 51A** for the attached Article for Reference)

- *MGH Burr Proton Center* – 2009 data provided by Massachusetts General Hospital (MGH) **(see Appendix 51-B in separate binder)** indicates that 77% of their patient volume is generated from the New England market. Using the 2010 U.S. Census Bureau Data, Table 1, below, shows that the population of New England is 14 million people. Because the MGH Burr Proton Center is the only proton therapy center in New England, the three treatment rooms at MGH provide services to a regional population of approximately 14 million people.

Table 1
New England 2010 Population

State	2010 Population
Massachusetts	6,547,629
New Hampshire	1,316,470
Vermont	625,741
Maine	1,328,361
Rhode Island	1,052,567
Connecticut	3,574,097
New England	**14,444,865**

- *University of Florida* – Data presented in a 2007 Bond Application showed that 32% of the University of Florida's three treatment room Proton Therapy Center's patient population was from within a 60 mile radius of the proton center, and 73% of the proton center's patient population was from within a 300 miles radius.

Using the experience of the successful Provision CON application and the actual experience of the established and successful MGH and Florida Proton Centers as a guide, we have defined the RSA for the Sibley Proton Project to include counties within a 100 mile radius of

Sibley Memorial Hospital, which includes a population of 14.3 million people. We estimate that about 70% of the Sibley proton therapy patients will be generated from this RSA. These RSA assumptions are consistent with and are supported by an analysis of the RSA used by existing and approved as well as in-development proton therapy centers.

Other Domestic Service Area (ODSA) – The ODSA is defined as all other market areas in the United States that are not included in the RSA. 20% of the proton therapy patients are expected to come from the ODSA. This projection is consistent with the actual experience of MGH Burr Proton Center 2009 data referenced in the RSA analysis, which shows that 16% of their patient population is from other U.S. markets outside of New England. This projection is also consistent with the markets served by The Johns Hopkins Hospital, where across all clinical programs 19% of inpatients seeking the expertise of the Johns Hopkins University sub-specialized physician Faculty originate from domestic markets outside of the state of Maryland. The Sibley Proton Therapy Center will be the proton therapy referral site for The Johns Hopkins Hospital and The Johns Hopkins Health System, and therefore must be able to provide care to this established Johns Hopkins Market. Access and facilitation of care for this market population is managed by Johns Hopkins USA, which was established as the result of this significant external market demand.

International Service Area (ISA) – The ISA is defined as all markets outside of the United States. 10% of the Sibley proton therapy patients are expected to originate from the ISA. This projection is consistent with the experience of MGH Burr Proton Center 2009 data referenced in the RSA analysis, which shows that 7% of their patient population is from the International Market. We think a slightly higher percentage for our center is reasonable given Sibley's location in Washington, D.C., and also given the international relationships Johns Hopkins Medicine has and resources related to serving international patients that we offer within our health system.

There are approximately 40 proton therapy centers in the world currently in operation that provide proton therapy to the world's cancer population. Though the global inventory of proton centers continues to grow, the supply is insufficient to meet demand. In addition to limited supply, proton centers are concentrated in the United States, Western Europe, China, and Japan. Patients from countries with no domestic access to proton therapy who have sufficient resources to travel in order to access proton therapy must travel outside of their home country to receive care. Not only is the Sibley Proton Project located in the world class city of Washington, D.C., but Johns Hopkins has invested significant resources to develop Johns Hopkins International (**JHI**), which has the specific aim to facilitate the global expansion of the Johns Hopkins Medicine Tripartite Mission. JHI accomplishes this aim by providing services to the international community, including providing a facilitation service for international patient to access Johns Hopkins University Faculty specialists and establishing partnerships in foreign healthcare industries. Through examples like these, JHI has established collaborations with over 15 international partners, promotes an international second opinion service, and facilitates nearly 17,000 outpatient visits and 750 inpatient admissions. Many of these international partnerships are in geographic locations with no access to Proton Therapy such as the Middle East and South America.

The Sibley Proton Project will be uniquely positioned as an International Destination for proton therapy. Sibley will be one of relatively few Full Scale Proton Therapy Centers operating in the world, and Sibley has the benefit of being located in Washington, D.C. Finally, the Sibley Proton Therapy Center will be directly staffed and supported by world-

class Johns Hopkins University Faculty, and it will be partnered with the established and growing JHI. This unique opportunity will establish the Sibley Proton Therapy Center and Washington, D.C. as a World-Class International Destination for Proton Therapy.

Regional Service Area Need Analysis

The Sibley Proton Project will operate in a Regional Service Area (the "**RSA**"), which is expected to generate 70% of the demand for proton therapy services, as discussed above. The Sibley Proton Project will provide proton therapy services to pediatric and adult cancer patients in this Regional Market that includes Washington, D.C., Northern Virginia, Central Maryland, Southern Pennsylvania, Delaware, and small portions of West Virginia and New Jersey. Table 2 provides the population in the RSA for the Sibley Proton Project.

Table 2
Population by County in Regional Service Area for the Sibley Proton Project

County	State	2010 Population
DISTRICT OF COLUMBIA	DC	601,723
Allegany	MD	75,087
Anne Arundel	MD	537,656
Baltimore	MD	805,029
Baltimore city	MD	620,961
CALVERT	MD	88,737
Caroline	MD	33,066
Carroll	MD	167,134
Cecil	MD	101,108
Charles	MD	146,551
Dorchester	MD	32,618
Frederick	MD	233,385
Harford	MD	244,826
Howard	MD	287,085
KENT	MD	20,197
Montgomery	MD	971,777
Prince George's	MD	863,420
Queen Anne's	MD	47,798
Somerset	MD	26,470
ST. MARY'S	MD	105,151
Talbot	MD	37,782
Washington	MD	147,430
Wicomico	MD	98,733
BERKELEY	WV	104,169
HAMPSHIRE	WV	23,964
HARDY	WV	14,025
JEFFERSON	WV	53,498
MINERAL	WV	28,212
MORGAN	WV	17,541
KENT	DE	162,310
NEW CASTLE	DE	538,479
SUSSEX	DE	197,145
Cumberland	NJ	156,898
Salem	NJ	66,083
ADAMS	PA	101,407
BEDFORD	PA	49,762
CHESTER	PA	498,886
CUMBERLAND	PA	235,406
DAUPHIN	PA	268,100
FRANKLIN	PA	149,618
FULTON	PA	14,845
HUNTINGDON	PA	45,913
LANCASTER	PA	519,445
LEBANON	PA	133,568
PERRY	PA	45,969
YORK	PA	434,972

County	State	2010 Population
ACCOMACK	VA	33,164
ALBEMARLE	VA	98,970
ALEXANDRIA CITY	VA	139,966
ARLINGTON	VA	207,627
CAROLINE	VA	28,545
CHARLOTTESVILLE CITY	VA	43,475
CLARKE	VA	14,034
CULPEPER	VA	46,689
ESSEX	VA	11,151
FAIRFAX	VA	1,081,726
FAIRFAX CITY	VA	22,565
FALLS CHURCH CITY	VA	12,332
FAUQUIER	VA	65,203
FLUVANNA	VA	25,691
FREDERICK	VA	233,385
FREDERICKSBURG CITY	VA	24,286
GOOCHLAND	VA	21,717
GREENE	VA	18,403
HANOVER	VA	99,863
HENRICO	VA	306,935
KING AND QUEEN	VA	6,945
KING GEORGE	VA	23,584
KING WILLIAM	VA	15,935
LANCASTER	VA	11,391
LOUDOUN	VA	312,311
LOUISA	VA	33,153
MADISON	VA	13,308
MANASSAS CITY	VA	37,821
MANASSAS PARK CITY	VA	14,273
MIDDLESEX	VA	10,959
NEW KENT	VA	18,429
NORTHUMBERLAND	VA	12,330
ORANGE	VA	33,481
PAGE	VA	24,042
PRINCE WILLIAM	VA	402,002
RAPPAHANNOCK	VA	7,373
RICHMOND	VA	9,254
RICHMOND CITY	VA	204,214
ROCKINGHAM	VA	76,314
SHENANDOAH	VA	41,993
SPOTSYLVANIA	VA	122,397
STAFFORD	VA	128,961
WARREN	VA	37,575
WESTMORELAND	VA	17,454
WINCHESTER CITY	VA	26,203
Total Regional Service Area		**14,331,368**

Regional Service Area Need Analysis Using the Health Care Advisory Board Model

The Health Care Advisory Board, a global research, technology and consulting firm that provides guidance and insights regarding the most challenging trends facing the healthcare industry, published a report entitled "Proton Beam Therapy – Energizing Technologies and Market Opportunities" ("the Advisory Board Report"). This Report presents a model for projecting need for Proton Beam Therapy. (See **Advisory Board Report at Appendix 51C**). According to the Advisory Board Report, the cancer incidence rate from the National Cancer Institute can be used to determine the projected number of proton treatment rooms needed for a defined population. In Table 3, we utilize the Advisory Board Report and the

model it offers to project the number of proton therapy treatment rooms needed for the RSA of the Sibley Proton Project. Applying the Advisory Board Report model to the RSA for the Sibley Proton Project results in an estimated need for 16.4 treatment rooms to serve Regional Service Area market.

Table 3
The Health Care Advisory Board Report Model

State	2010 Total Population (1)	Total Cancer Incidence Rate (2)	Projected New Cancer Patients	Projected Radiation Patients (3)	Projected Proton Eligible Patients (3)	Full Scale Proton Centers Needed (3)	Number of Treatment Rooms Needed (4)
Washington, DC	601,723	459.2	2,763	1,382	207	0.2	0.8
Delaware	*897,934*	*516.3*	*4,636*	*2,319*	*348*	*0.3*	*1.2*
Maryland	5,692,001	453.0	25,784	12,895	1,934	1.6	6.4
New Jersey	222,981	501.4	1,118	599	84	0.1	0.4
Pennsylvania	2,497,891	480.2	11,994	6,000	899	0.7	2.8
Virginia	4,177,429	437.4	18,272	9,149	1,375	1.1	4.4
West Virginia	241,409	461.0	1,113	558	84	0.1	0.4
Total RSA	**14,331,368**	**458.3**	**65,680**	**32,862**	**4,931**	**4.1**	**16.4**

In the Advisory Board Report model, the projected number of new cancer patients is calculated using data from the National Cancer Institute SEER Cancer incidence rate per 100,000 population per year.[3] As a result, in Table 3, we calculate the Projected New Cancer Patients by multiplying the population data from the RSA by the Cancer Incidence Rate, which results in a projected 65,680 new cancer cases. Following the Advisory Board Report model, 50% of cancer cases are expected to require radiation treatment. This Advisory Board assumption for the radiation rate is a conservative approach, as the radiation rate suggested by the American Society for Radiation Oncology (ASTRO) is closer to 66%[4] and the radiation rate projection by the National Cancer Institute (NCI) is about 60%[5].

[3] The SEER reporting program was established as the result of the National Cancer Act of 1971 mandated the *collection, analysis, and dissemination of data useful in the prevention, diagnosis, and treatment of cancer.* See the SEER Cancer website http://seer.cancer.gov/csr/1975_2009_pops09/results_figure/sect_01_intro2_24pgs.pdf.

[4] ASTRO is the largest radiation oncology organization in the world and has the stated mission to improve patient care through education, clinical practice, advancement of science and advocacy. See the ASTRO website http://www.answers.org/satistics/about radiation therapy.ASPX.

[5] The NCI is an agency of the National Institute of Health that was established under the National Cancer Institute Act of 1937 as the Federal Government's principal agency for cancer research and training.See the National Cancer Institute website http://www.cancer.gov/cancertopics/coping/radiation-therapy-and-you/page2

Applying the Advisory Board Report radiation rate to the estimated number of cancer cases yields 32,862 (65,680 x .50) projected Radiation Therapy Patients. Significantly, the ASTRO radiation rate would project the number of radiation patients to be closer to 43,000 patients, and the NCI radiation rate would project the number of radiation patients to be closer to 39,000 patients.

The Advisory Board Report applies a 15% rate to determine the number of radiation therapy patients that would be eligible for proton therapy. This rate is consistent with a widely reported study conducted in Sweden (the "Swedish Study")[6]. See **Appendix 51D**. According to the Swedish Study, 15% of the radiation oncology patients in Sweden are eligible for proton therapy.

Applying the Advisory Board Report model to the Sibley RSA results in a projected number of eligible proton patients of 4,931 (32,862 x 15%). Applying instead the ASTRO rate, the estimated number of eligible proton patients increases to 6,500 patients, and using the NCI rate, the estimated number of eligible proton patients increases to 5,900 patients.

The Advisory Report model was developed around what the report labels a "Large Scale Center" or a "Full Scale Center." All of these centers have between three and five treatment rooms, as indicated in Table 3. In contrast to Large Scale Centers and Full Scale Centers, the Advisory Board Report discusses Small Scale technology, which is proton therapy technology that is more compact and provides treatment room capacity of only one or two rooms. This technology is not incorporated into the Advisory Board Report Model because this technology is not currently used to treat patients. Small Scale Technology is being introduced by new vendor entrants into the market, as well as a few established vendors. Most of the Small Scale Technology is different technology than that used in the Large Scale Centers. Though a small number of Small Scale Technology vendors have started receiving FDA approval, the technology is unproven as it has yet to be used clinically to treat patients. Though more than twelve Small Scale Centers have announced their intent to enter the Proton Therapy Market, there are no small scale centers currently treating patients in the United States.

Applying the Advisory Board Report Model to the Sibley Proton Project RSA results in a projected need of 4.1 Full Scale Centers, or about 16.4 proton therapy treatment rooms. See Table 3. Significantly, using the ASTRO data, the projected number of proton therapy treatment rooms needed increases to 22 rooms, and using the NCI data, the projected number of needed proton therapy treatment rooms increases to 20 rooms.

In summary, when the Advisory Board Report model for projecting need is applied to 2010 census data for Sibley's Regional Service Area, using National Cancer Institute incidence of disease data, the estimated number of treatment rooms needed to serve the population in the regional service area of Sibley far exceeds the four treatment rooms planned for the Sibley Proton Project.

Regional Service Area Need Analysis Using the Sg2 Growth Projections

[6] The Swedish Study was published in ACTA Oncology.

The Sibley Proton Project projections above were calculated assuming static demand for proton therapy services over time. These projections do not account for growth in demand for proton therapy over the next 10 years. The Sg2 Projections account for growth in proton therapy services using a proprietary market analysis tool. (The "Sg2 Model"). This proprietary market analysis tool takes into account studies of population trends, national and regional regulatory trends, such as payment policies and quality initiatives, and market trends, such as innovations in care and technology.

Sg2 is a Health Care Intelligence firm that provides advanced analytics, business intelligence, and education with the goal of supporting improved care delivery and organizational performance of its health care partners. In its 2012 report, *Delivering Growth and Value in Cancer by Integrating Care Across the Continuum* (Attached as **Appendix 51 E**), Sg2 projects that the need for outpatient cancer services will grow by 31% over the next 10 years. It projects that specifically radiation therapy for outpatient cancer services will only grow by 13%. This reduction is due to expected practice changes in some of the radiation therapy modalities other than proton therapy. The Report indicates that radiation therapy services are expected to grow by 22% based solely on population growth. We believe sufficient information is not available in the field of proton therapy at this time to predict reasonably accurately the utilization growth rate for radiation therapy services beyond simple population growth. Therefore, for our analysis, we believe the most appropriate growth rate to apply to proton therapy is the population growth rate-based 22%.

To apply the Sg2 Model for growth to the RSA population for the Sibley Proton Project, we start with the 2010 Projected Eligible Proton Therapy Patients, shown in Table 4, and apply the Sg2 Model growth rate, which yields 6,016 Projected Eligible Proton Therapy Patients in the year 2020. Based on the Sg2 projections, the demand for cancer services over the next 10 years is significant. Using the same calculation to convert patients into needed treatment rooms that was used above in Table 3, the 6,016 Projected Eligible Proton Therapy Patients results in a projected need of 20.0 treatment rooms.

Table 4 also shows the projected number of eligible proton therapy patients in 2020 for the Sibley Proton Project RSA when the Sg2 projected 10 year growth rate is applied to projected 2010 proton eligible patients calculated using three different assumptions about the proportion of cancer cases that would benefit from radiation therapy: Health Care Advisory Board Model (50%), ASTRO assumption (66%), and the NCI assumption (60%). These different methodologies project need ranging from 20.8 to 26.4 treatment rooms in 2020. These numbers are far in excess of the four treatment rooms proposed in this project.

Table 4
Sg2 Model Projects with Alternative Assumptions

NEED MODEL	2010 PROJECTED ELIGIBLE PROTON THERAPY PATIENTS	SG2 PROJECTED 10 YEAR GROWTH RATE	2020 PROJECTED ELIGIBLE PROTON THERAPY PATIENTS	2020 PROJECTED FULL SCALE CENTERS NEEDED	2020 PROJECTED TREATMENT ROOMS NEEDED
Health Care Advisory Board Model	4,931	22%	6,016	5.0	20.8
Advisory Board Model with the ASTRO assumption	6,500	22%	7,930	6.6	26.4
Advisory Board Model with the NCI assumption	5,900	22%	7,198	6.0	24.0

The Sibley Proton Project RSA is a robust region of care that includes several sub-markets of high density populations such as the Washington, D.C. Market, the Baltimore Market, the Richmond Market, and the York-Lancaster Market. The Sibley Proton Project will construct a 4 treatment room facility in Washington, D.C., so the Washington, D.C. Market represents a RSA sub-market population of critical importance to the Sibley Proton Project. With the Washington, D.C. Market population of 5.5 million people having the most proximal access to the Sibley Proton Therapy Center, this Market represents the Sibley Proton Project's Primary Service Area (PSA).

Primary Service Area Need Analysis

As a subset of the Regional Service Area ("**RSA**"), the Sibley Proton Project will operate in a Primary Service Area (the "**PSA**"), which accounts for approximately 40% of the demand for proton therapy services as indicated in Table 5.

Table 5
Comparative Size of the PSA within the RSA

	2010 Population	Projected 2010 Cancer Cases
Regional Service Area (RSA)	14,331,368	65,680
Primary Service Area (PSA)	5,582,170	23,547
PSA % of RSA	**39%**	**36%**

Table 5 shows that the Primary Service Area comprises 39% of the population in the Regional Service Area with an estimated 36% of the cancer cases.

The Sibley Proton Project will provide therapy services to pediatric and adult cancer patients in the local Washington, D.C. Market, defined as the counties included in the US Census Bureau's Metropolitan Statistical Area of Washington-Arlington-Alexandria, DC-VA-MD-WV. These data are from "Counties with Metropolitan and Micropolitan Statistical Area Codes, December 2009" located on the following web site: http://www.census.gov/population/metro/data/def.html. The Metropolitan Statistical Area (the "MSA") is equivalent to the PSA and includes the following counties (the population is shown in Table 6, below):

a. Washington, DC
b. Maryland Counties: Calvert, Charles, Frederick, Montgomery, Prince George's
c. Virginia Counties: Arlington, Clarke, Fairfax, Fauquier, Loudon, Prince William, Spotsylvania, Stafford, Warren, Alexandria City, Fairfax City, Falls Church City, Fredericksburg City, Manassas City, and Manassas Park City
d. West Virginia: Jefferson

Table 6
Primary Service Area for Sibley Proton Project

County	State	2010 Population
District of Columbia	DC	601,723
Calvert	MD	88,737
Charles	MD	146,551
Frederick	MD	233,385
Montgomery	MD	971,777
Prince George's	MD	863,420
Arlington	VA	207,627
Clarke	VA	14,034
Fairfax	VA	1,081,726
Fauquier	VA	65,203
Loudon	VA	312,311
Prince William	VA	402,002
Spotsylvania	VA	122,397
Stafford	VA	128,961
Warren	VA	37,575
Alexandria City	VA	139,966
Fairfax City	VA	22,565
Falls Church City	VA	12,332
Fredericksburg City	VA	24,286
Manassas City	VA	37,821
Manassas Park City	VA	14,273
Jefferson	WV	53,498
Total PSA		**5,582,170**

The following analysis demonstrates that, while the appropriate area to use as the market for a specialized service like Proton Therapy is the larger Regional Service Area, there is sufficient demand to justify our four treatment room project in the Primary Service Area alone.

Primary Service Area Need Analysis for Established Proton Therapy Centers

Table 7 identifies the Established Proton Therapy Centers in the United States and provides applicable analytical data. Established Proton Therapy Centers (EPTCs) are centers that have been in existence for 5 or more years. EPTCs have an operational track record, are past the start-up period and are generally more stable than newer centers. At the bottom of the table we show the proposed Sibley Proton Therapy Center, using both the full 4-treatment room capacity and also the 3-treatment room capacity that is expected to apply, with the remaining room used for clinical research.

Table 7
Established Proton Therapy Centers

Established Proton Therapy Center (EPTC)	Year of Operation	Treatment Rooms[7]	MSA	2010 Population[8]	Population per Treatment Room	Operating Hours[9]
Loma Linda University	1990	4	Riverside – San Bernardino – Ontario	4,224,851	1,056,213	17
Massachusetts General Hospital	2001	3	Boston – Cambridge – Quincy	4,552,402	1,517,467	10
Midwest Proton Radiotherapy Institute (MPRI)	2004	3	Bloomington and Indianapolis – Carmel	1,948,955	649,652	12
M.D. Anderson	2006	4	Houston – Sugar Land – Baytown	5,946,800	1,486,700	11.5
University of Florida	2006	3	Jacksonville	1,345,596	448,532	16
EPTC Average		**3.4**		**3,603,721**	**1,031,713**	**13**
PROPOSED Sibley Proton Therapy Center, including all 4 treatment room		4	Washington, D.C.	5,558,000	1,395,000	10
PROPOSED Sibley Proton Therapy Center, three treatment rooms excluding research-only		3	Washington, D.C.	5,580,000	1,860,000	13

Based on the data in Table 7, all 5 of the EPTCs operate three to four proton therapy treatment rooms within an average MSA population of 3.60 million people and the average population per treatment room of 1.03 million people. With a population of 5.58 million and an average population per treatment room ranging from 1.39 to 1.86 million people, the

[7] The number of treatment rooms for each center is based on web based research and/or conversation with the particular EPTC.
[8] The Metropolitan Statistical Areas are the primary service areas for the Centers and the population for such areas is based on the 2010 U.S. Census Bureau data.
[9] The operating hours are based upon published data from either the Health Care Advisory Board Report entitled "Proton Beam Therapy – Emerging Technologies and Market Opportunities" or from the particular EPTC website. The Health Care Advisory Board is a global research, technology, and consulting firm that provide guidance and insights on the most challenging trends facing healthcare. Further information can be found on their web site, http://www.advisory.com/About-Us. The Health Care Advisory Report is provided as Appendix B.

Primary Service Area of the Sibley Proton Project and the Sibley Proton Project treatment room capacity fits squarely in the population range of these successful EPTCs that all operate between 3 and 4 treatment rooms.

In addition, Table 7 shows that EPTCs maintain operating hours that average 13 hours per day. The operating hours are based upon published data from either the Health Care Advisory Board Report entitled "Proton Beam Therapy – Emerging Technologies and Market Opportunities" or from that EPTC's website. The Sibley Proton Project plans to operate approximately 13 hours per day[10]. Thus, the treatment room capacity of the Sibley Proton Project is consistent with that of all the EPTCs.

Primary Service Area Need Analysis Using the Health Care Advisory Board Model

As reviewed above, that the Health Care Advisory Board Report developed a model for projecting need for Proton Beam Therapy. (See Advisory Board Report, **Appendix 51C)**. According to the Advisory Board Report, the cancer incidence rate as reported by the National Cancer Institute can be used to determine the projected number of proton treatment rooms needed for a defined population. The Advisory Board Report model is a sophisticated methodology that utilizes actual population data and published cancer incidence and research data that are supported by research studies to calculate the proton therapy need for a population.

In Table 8, we utilize the Advisory Board Report and the model it developed to project the number of proton therapy treatment rooms needed for the PSA of the Sibley Proton Project. Applying the Advisory Board Report model to the PSA for the Sibley Proton Project results in a projected 6 treatment rooms needed to serve Washington DC MSA market.[11]

[10] Clinical operating hours per day = Projected clinical treatment hours per day/ Sibley Proton Project's 3 clinical treatment rooms. When applying this calculation to the pro forma data, the Center requires an average 13 hours of clinical operations per day. If the 1 research treatment room was added to the calculation, then the Center's 4 treatment rooms would have an equivalent clinical operating time of 10 hours per day.

[11] The formulas applied in the table are the same as those used above. Cancer incidence rate is applied to the population to estimated new cancer cases. Consistent with the Health Care Advisory Board model, 50% of those cases are assumed to be eligible for radiation therapy, and 15% of those cases are assumed eligible for proton therapy.

Table 8
The Health Care Advisory Board Model

STATE	COUNTY	2010 TOTAL POPULATION (1)	TOTAL CANCER INCIDENCE RATE (2)	PROJECTED NEW CANCER PATIENTS	PROJECTED RADIATION PATIENTS	PROJECTED PROTON ELIGIBLE PATIENTS (3)	FULL SCALE PROTON CENTERS NEEDED (3)	NUMBER OF TREATMENT ROOMS NEEDED (4)
DC	District of Columbia	601,723	459.2	2,763	1,382	207	0.2	0.8
MD	Calvert	88,737	474.0	421	211	32	0	0
MD	Charles	146,551	431.5	632	316	47	0	0
MD	Frederick	233,385	491.8	1,148	574	86	0.1	0.4
MD	Montgomery	971,777	406.7	3,952	1,976	296	0.2	0.8
MD	Prince George's	863,420	408.1	3,524	1,762	264	0.2	0.8
VA	Arlington	207,627	372.8	774	387	58	0	0
VA	Clark	14,034	425.8	60	30	5	0	0
VA	Fairfax	1,081,726	402.5	4,354	2,177	327	0.3	1.2
V	Fauquier	65,203	420.6	274	137	21	0	0
VA	Loudon	312,311	408.9	1,277	6396	96	0.1	0.4
VA	Prince William	402,002	426.7	1,715	858	129	0.1	0.4
VA	Spotsylvania	122,397	518.0	634	317	48	0	0
VA	Stafford	128,961	518.6	669	335	50	0	0
VA	Warren	37,575	461.6	173	87	13	0	0
VA	Alexandria City	139,966	344.7	482	241	36	0	0
VA	Fairfax City	22,565	385.9	87	44	7	0	0
VA	Falls Church City	12,332	391.9	48	24	4	0	0
VA	Fredericksburg City	24,286	521.3	127	64	10	0	0
VA	Manassas City	37,821	385.5	146	73	11	0	0
VA	Manassas Park City	14,273	494.4	71	36	5	0	0
WV	Jefferson	53,498	403.3	216	108	16	0	0
	Total Region	**5,582,170**	**421.8**	**23,547**	**11,778**	**1,752**	**1.5**	**6.0**

Applying the Advisory Board Report model to the PSA for the Sibley Proton Project results in a need of 1.5 Full Scale Centers, or about 6 proton therapy treatment rooms. See Table

8. Using the alternative ASTRO and NCI assumptions for radiation therapy eligibility rates as discussed in the RSA Analysis, the number of proton therapy treatment rooms needed using the ASTRO data is 8 and the number of proton therapy treatment rooms using the NCI data is 7. Consequently, under the Advisory Board Report model, the Sibley Proton Project's 4 treatment rooms are more than justified.

Primary Service Area Need Analysis Using the Sg2 Growth Projections

The Sibley Proton Project PSA projections thus far have been calculated based upon a static demand for proton therapy services over time, and do not account for growth. The Sg2 model is a proprietary market analysis that includes studies of population trends, national and regional regulatory trends, such as payment policies and quality initiatives and market trends, such as innovations in care and technology. Just as we did for the RSA analysis above, below we apply the growth rate suggested by Sg2 to try to more accurately predict demand for proton therapy in the future. When the growth rate is applied to the static 2010 need projections for the PSA and the Health Care Advisory Board model estimates of radiation therapy cases, the projected number of needed proton therapy treatment rooms increases from 6 to 7.2 treatment rooms by 2020. The results are shown in Table 9 below. Just as in the RSA analysis, using the ASTRO and NCI alternative assumptions about radiation therapy eligibility rates results in a higher projected need, for 9.2 and 8.4 treatment rooms, respectively.

Table 9
Need Projections with Sg2 Growth Rate

Need Model	2010 Projected Eligible Proton Therapy Patients	Sg2 Projected 10 Year Growth Rate	2010 Projected Eligible Proton Therapy Patients	2010 Projected Full Scale Centers Needed	2010 Projected Treatment Rooms Needed
Health Care Advisory Board Model	1,752	22%	2,137	1.8	7.2
Advisory Board Model with the NCI Assumption	2,100	22%	2,562	2.1	8.4
Advisory Board Model with the ASTRO Assumption	2,300	22%	2,806	2.3	9.2

Tumor Specific Market Need for Proton Therapy

As described in detail above, there will be more demand for proton therapy than the Sibley Proton Therapy Center will have the capacity to treat. How this valuable resource will be allocated will be directed by our clinical programming. We model our clinical programs based on a comprehensive evaluation of existing proton therapy programs, targeted

evaluations of peer academic proton therapy programs, particularly Massachusetts General Hospital (MGH), evidence-based research supporting the clinical efficacy by cancer diagnosis, integration of proton therapy with multi-disciplinary cancer therapies, and opportunities to advance the study and development of proton therapy.

MGH Evaluation

We conducted an analysis of Massachusetts General Hospital's Burr Proton Center (MGH) to guide our planning with respect to, among other things, our clinical program (what kind of cases we expect to treat). The MGH proton therapy program has been treating patients since 2001, and it has served as a model for our planning because of its comprehensive academic focus, similar to our plans.

One of the key tools used at MGH is the "Proton Rounds", where potential proton therapy cases are peer-reviewed and clinical trial eligibility is assessed for each case. The Proton Rounds process helps to ensure that patients with the greatest need for proton therapy, as indicated by evidence-based research relevant to their particular age, tumor type, and other clinical circumstances, have access to the limited proton therapy resources. An analysis of the 2009 MGH proton volume shows that of 844 cases, 18% were pediatrics, 29% were sarcoma, 26% were central nervous system, and 6% were head and neck. Our review and analysis of the proton therapy program at MGH led to the following conclusions:

- The Sibley Proton Therapy Center seeks to emulate the MGH model, particularly with respect to the implementation of a robust academic model.
- The Sibley Proton Therapy Center will not have sufficient capacity to meet the demand projected in the market, which in the short term is projected conservatively to be 4 proton therapy treatment rooms in the Primary Service Area and 16 proton therapy treatment rooms in the Regional Service Area.
- Utilization of Proton Therapy in the development of personalized treatment plans is optimal if applied in an academic setting. In an academic setting personalized treatment plans are created by a team of sub-specialists who work together routinely to provide patients with the highest quality comprehensive and innovative treatments.
- The Sibley Proton Therapy Center will develop a robust inventory of available clinical trials for patients, and each patient receiving proton therapy will be evaluated for accrual to a clinical trial protocol.
- Because the capacity of the Sibley Proton Therapy Center will be a limited resource, the focus of care should be on the most acute patients where there is evidence-based research to support the efficacy of proton therapy over traditional radiation therapy.

Table 10 provides tumor specific projections of radiation therapy cases for the Regional Service Area.

Table 10
2017 Projected Cancer Volumes – Regional Service Area

	MD	VA	PA	DE	DC	WV	NJ	Total RSA
Population:								
Adult	4,325,911	3,033,573	1,382,938	520,160	481,101	182,017	18,617	9,944,317
Pediatric	1,525,325	1,124,900	477,734	197,472	145,690	63,547	6,280	3,540,948
Total Population	**5,851,236**	**4,158,473**	**1,860,672**	**717,632**	**626,791**	**245,564**	**24,897**	**13,485,265**
Projected Cancer Cases								
Pediatric	**233**	**182**	**86**	**36**	**22**	**9**	**1**	**569**
Adult:								
Brain and Spine	267	184	99	38	30	11	1	632
Lung	2,792	1,779	878	407	281	151	13	6,301
Head and Neck	413	303	132	58	61	22	2	991
Prostate	3,248	2,221	903	471	414	108	16	7,381
Pancreas	539	337	156	68	65	17	3	1,186
Liver	260	192	71	33	44	11	1	612
Total Adult	**7,519**	**5,016**	**2,241**	**1,075**	**896**	**321**	**36**	**17,104**
Total Cancer Cases	**7,752**	**5,198**	**2,327**	**1,111**	**917**	**331**	**38**	**17,673**
Projected Radiation Cases								
Pediatric	**72**	**56**	**27**	**11**	**7**	**3**	**0**	**176**
Adult:								
Brain and Spine	160	110	60	23	18	7	1	379
Lung	1,675	1,067	527	244	169	90	8	3,781
Head and Neck	248	182	79	35	37	13	1	595
Prostate	1,949	1,333	542	282	249	65	9	4,429
Pancreas	324	202	94	41	39	10	2	712
Liver	156	115	43	20	26	7	1	367
Total Adult	**4,511**	**3,009**	**1,344**	**645**	**537**	**193**	**22**	**10,262**
Total Radiation Cases	**4,584**	**3,066**	**1,371**	**656**	**544**	**196**	**22**	**10,439**

*Projected radiation cases are calculated as 31% of pediatric cases and 60% of adult cases for all tumor types. See Swedish study for the basis for these percentages.

Insufficient conclusive evidence currently exists to reliably predict what percentage of cases of each of these types of cancers will benefit from proton therapy. Some clinician experts estimate that as much as 80% of the pediatric cases determined to be radiation cases would be selected for proton therapy if it were available. A firmer estimate of this percentage is an example of the kind of information we hope to produce in a rigorous academic clinical/research environment. We know that the percentage of the adult cases likely to be referred to and to benefit from proton therapy would vary widely. We expect a high percentage of brain and spine cases and head and neck cases, based on the existing evidence. What is clear from Table 10, though, is that in the Sibley Proton Therapy Center Regional Service Area, by 2017, there will be many times more cases that would benefit from proton therapy than there will be capacity to treat at the Sibley Proton Therapy Center in our proposed 4 treatment room facility. This table demonstrates that there is not just sufficient numbers of cancer cases to fill the facility, but that there are sufficient numbers of cases in the categories where the current evidence-base is the strongest and where the next critical questions need to be answered regarding proton therapy efficacy.

Putting It All Together: Market Demand, Clinical Programming, and Proton Center Capacity

Planning around a possible Sibley Proton Therapy Center has been a multi-year process based on an intricate combination of determining that there is sufficient demand in the market to justify the investment, that this demand is not generic, but is sufficient specifically in the areas where our clinicians feel the investment is justified by current evidence-based need or by a need for new knowledge. We also had to do a self-assessment and determine the commitment of our entire delivery system, and determine the appropriate capacity for the project. Through all of the complexities of this planning, the beauty of the Sibley Proton Therapy Center is the simplicity of its core mission: to bring the proven history and power of the academic John Hopkins Tripartite Mission to Washington, D.C. and the campus of Sibley, with its commitment to patients, community, and service, and develop a patient-centric Proton Therapy Center to meet this unmet and growing clinical and research need.

Summary

Demand for proton therapy currently exceeds capacity. Demand is predicted to grow due to population growth, an increase in the incidence of cancer predicted for the future, and growing evidence about the types of cases that would benefit from this specialized service. The Sibley Proton Project proposes to develop a four treatment room facility. While proton therapy is considered a regional service, and would also draw from the Other Domestic Service Area and International Service Area, the demand for the service in the much smaller Primary Service Area will exceed the capacity of the Sibley Proton Therapy Center's four treatment rooms at the time that the Center opens. Clearly, Proton therapy is a needed service, and the proposed facility is well-located and well-positioned through its many partnerships to meet the demand as effectively as possible, guided by the tripartite mission of excellence in clinical care, research, and training.

As stated Above, Sibley, Johns Hopkins, Children's National Medical Center, and Howard University Hospital, all who have an established history of providing World-Class Oncology Leadership and Oncology Care to the patients of Washington, D.C., of the Sibley Project's Primary and Regional Service Area, and of Out of Region Domestic and International populations, are committed and have the resources to build a world-class Proton Therapy Center in the world-class city of Washington, D.C.

52. In the case of a reduction, elimination, or relocation of a service discuss the need that the population presently served has for the service or facility, the extent to which that need will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service or facility on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, other underserved groups, and the elderly to obtain needed health care.

Response:

This question not applicable per CON checklist

53. Discuss the extent to which medically underserved populations (low-income persons, racial and ethnic minorities, women, handicapped persons and other underserved groups and the elderly) currently use your services in comparison to the percentage of the population in your service area which is in these categories. Discuss the extent to which the proposed project will affect the extent to which medically underserved populations can be expected to use your services if your application is approved.

Response:

The proton site will meet ADA guidelines for handicapped patients and will use the Federal Sliding Fee schedule for those without insurance.

It is important to define the underserved population in the Washington, D.C. region, and this base on the ease of access to proton therapy. There is no access to proton therapy in the Washington, D.C., Northern Virginia, and Baltimore regions. The closest proton therapy centers are in Philadelphia to the north or Hampton, VA to the South. Each is over 100 miles away from Washington, D.C., and when considering that a proton therapy patient will be receiving daily treatment for six weeks on average, it is unrealistic to think that a patient and the patient's family can devote resources for daily travel. In fact with this extended distance, the only patients who are able to access proton therapy are those who have the resources to relocate away from their homes and family support system for the six week treatment time. This is a significant personal cost to the patient, and it creates a barrier to access proton therapy. This access barrier results in the entire population of Washington, D.C. being underserved.

The Sibley Proton Therapy Center will be located on the campus of Sibley Memorial Hospital and will provide direct access to the entire underserved population in the Washington, D.C. region. Though the Proton Center will be located at Sibley, it will serve a much broader market as defined in the response to Question 51. This market is extended beyond the historical Sibley market because the limited supply of this highly sophisticated technology drives regional demand in addition to local demand. In addition, the Sibley Proton Therapy Center will be the proton therapy referral site for the Johns Hopkins Health System which has an extensive mid-Atlantic breadth. Finally, the Sibley Proton Therapy Center will be directly integrated with the Johns Hopkins Sibley Kimmel Comprehensive Cancer Center, which in 2012 was ranked as the #3 Cancer Hospital in the country by the US New and World Report. This integration with the SKCCC includes integrated multidisciplinary clinical cancer programs and access to innovative clinical trial research, all of which is led and managed by world renowned Johns Hopkins University Faculty. The cancer expertise and programming provided by the SKCCC and integrated with the Sibley Proton Therapy Center will create a regional demand for proton therapy at Sibley

The Strategic Partnerships that are being developed with Children's National Medical Center and Howard University Hospital will ensure that the broader underserved Washington, D.C. population will have access to Proton Therapy. The partnership with Children's National Medical Center will integrate the clinical oncology programs, oncology research programs, and training programs with the radiation therapy and proton therapy programs at Sibley. It is planned that one of the four treatment rooms, 25% of the Sibley

Proton Therapy Center capacity, will be devoted to the treatment of the underserved pediatric cancer patients in Washington, D.C. and the Region. The partnership with Howard University Hospital will develop collaborations in research, training, and clinical care that will provide the Howard University Hospital patient population with access to the Sibley Proton Therapy Center. Partnership discussions have included the development of a logistical program to ensure that Howard University Hospital patient can increase the ease of access to Sibley Memorial Hospital. The discussions have also included the development of Johns Hopkins Proton Therapy consultation and follow-up clinics in the Howard University Hospital community so that the burden of transportation for follow-up care can be minimized for the Howard University Hospital Population.

Because the provision of proton therapy access to the underserved population of Washington, D.C. and the region is at the core of the Sibley Proton Therapy Center and the Johns Hopkins Medicine Missions, these access programs and partnership programs are integrated into the Business Planning for the Sibley Proton Therapy Center. This is directly evident in our projection of Payor Mix. The historical Sibley payor mix includes 1.4% Medicaid and 2.5% Self Pay and Charity care. The Sibley Proton Therapy Center payor mix adjusts these figures 12% Medicaid and 5% Charity care to account for broader access and our partnerships. The overall effect on the Sibley payor mix is shown in the response to question 30.

In addition, we have included in **Appendix 53** a graphic showing Sibley's commitment to charity care over the past several years. Sibley has always met its obligation to the District of Columbia for uncompensated care, as is referenced below in question 54. It is expected that the Sibley Proton Therapy Center will only enhance our committed to access and the resulting uncompensated care.

54. Discuss your past performance in meeting your obligation, if any, under applicable federal and District regulations requiring provision of uncompensated care, community service or access by minorities and handicapped persons to health programs, facilities and services (including the existence of any civil rights access complaints against you.)

Response:

Sibley Memorial Hospital has exceeded its obligation for the provision of uncompensated care.

For documentation of Sibley's uncompensated care commitment and uncompensated care report, see **Appendix 54A**. Also see related graphic **Appendix 53A** referenced in Question 53.

Sibley is not aware of any pending civil rights access complaints.

55. Discuss the range of means by which a person has or will have access to your services. NOTE: Regulations require that SHPDA consider the accessibility of services to members of medically underserved groups. The regulations further specify that access to services can be through a variety of means including use of outpatient services, admission by house staff, admission by personal physician, etc.

Response:
Proton therapy is usually additive therapy to standard radiation oncology treatments. Routinely, when proton is available, these modalities work in conjunction with one another to treat the patient with increased success.

Other Sibley support services, including but not limited to housekeeping, laundry, medical supply, laboratory, pharmacy, diagnostic imaging, dietary, medical records, and infection control will continue to be provided as they are currently at Sibley.

The Value of the Johns Hopkins System of Care is significant, and while not contained within the campus of Sibley Memorial Hospital is it a significant link to the overall system of care necessary to treat the entire oncology patient.

In Sg2's "Cancer Forecast: Managing the Change" **Appendix 51G**, they state that the success of a cancer program will depend on its ability to connect with a system of care. With this in mind, the following healthcare trends are becoming more prevalent in the market.

- Care is being driven out of the inpatient hospital setting and into the outpatient setting.
- There is an emphasis to drive acute care service out of high cost tertiary care settings.
- Quality is an imperative throughout a patient's continuum of care.

It will take a well integrated system of cancer care to respond to these healthcare trends and succeed as a comprehensive cancer program.

Such a System of Care is directly applicable to the development of a successful proton therapy program due to the highly specialized use of the technology and the high capital and operational costs. Johns Hopkins Medicine is a very unique System of Care that is well position to succeed in providing comprehensive, academic based cancer care and to succeed in providing the community with an academic based proton therapy program.

Primary Care: Johns Hopkins Community Physicians (JHCP) is the Division of Johns Hopkins Medicine that manages primary care for the population in Maryland and D.C.. JHCP has clinical operations in 32 locations across Maryland and the District of Columbia, and the JHCP physicians manage the primary care for 320,000 adult and pediatric patients, resulting in approximately 800,000 visits annually. Specifically, aligned with Sibley, JHCP has offices in Sibley's Medical Building. JCHP also intends to have primary care physicians located on Eye Street in the District of Columbia. (see detail in CON 12-2-4)

Community Hospitals: Through Johns Hopkins Health System, Johns Hopkins manages acute and tertiary care at Sibley Memorial Hospital, Suburban Hospital,

Howard County General Hospital, and All Children's Hospital in Florida. The Johns Hopkins Community hospitals provide care for 49,000 admissions and 540,000 outpatient visits annually.

Academic Medical Centers: The Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center are the Academic Medical centers that provide acute, tertiary, and quaternary care in an academic setting, combining clinical care, research, and teaching. The Johns Hopkins Academic Medical Centers provide care for 67,000 admissions and 625,000 outpatient visits annually.

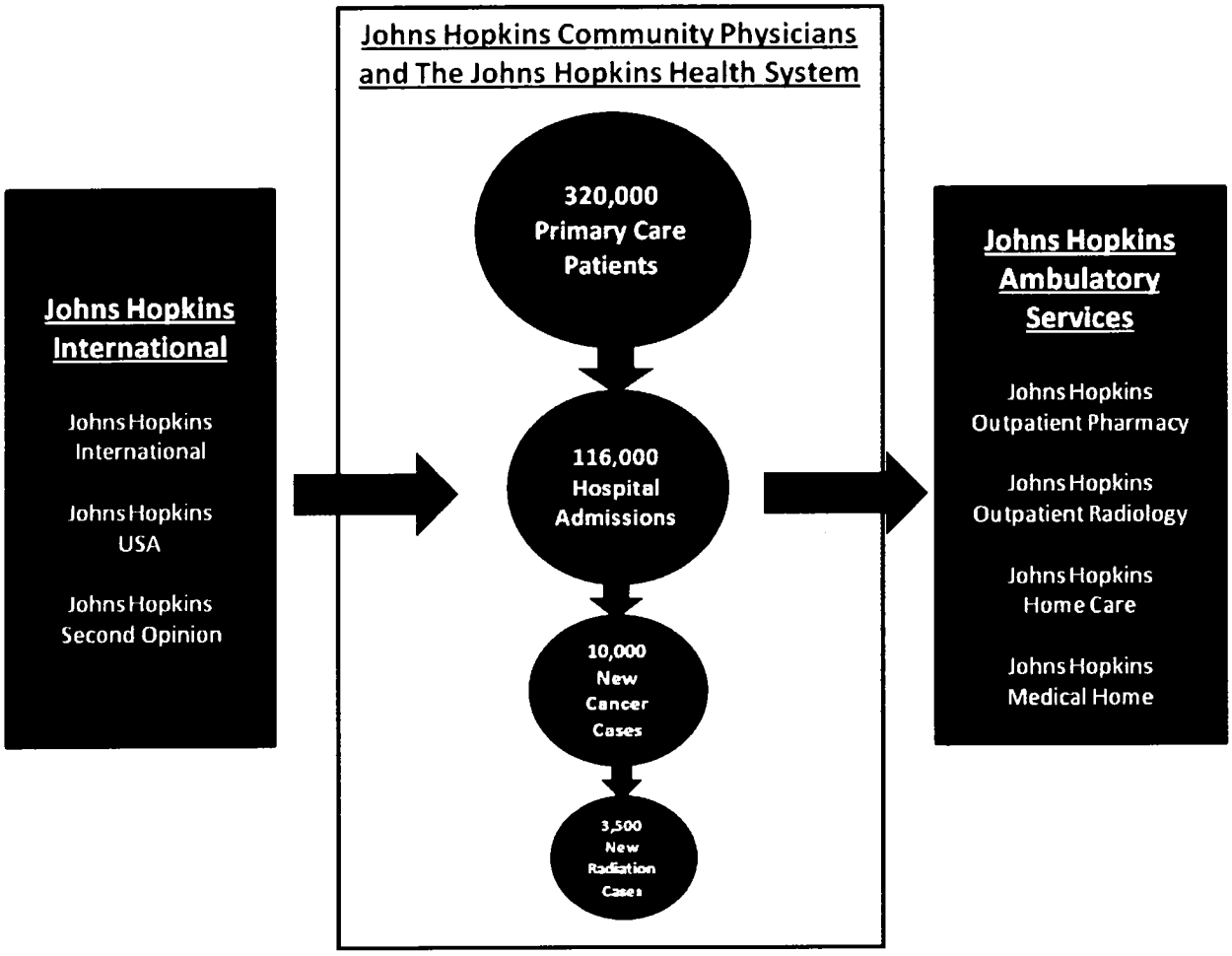
Cancer Care: The flagship comprehensive cancer program for Johns Hopkins is the Sidney Kimmel Comprehensive Cancer Center located at the Johns Hopkins Hospital, where 6,800 new cancer cases are managed annually. Medical Oncology and Radiation Oncology services are also provided at Johns Hopkins Bayview Medical Center, Howard County General Hospital, Suburban Hospital and Sibley Hospital, and these Johns Hopkins cancer programs manage 3,300 new cancer cases annually. Of The 10,100 cancer cases managed by Johns Hopkins, 3,500 of these new cancer cases receive radiation therapy services at a Johns Hopkins Radiation Oncology site.

This system of care is supported by Johns Hopkins International and Johns Hopkins USA who assist in providing access to patients from outside of our primary regional service area. These out of region patients are seeking the expert clinical care, innovative clinical trials, and unique tertiary and quaternary services provided by Johns Hopkins System clinical care teams. This Johns Hopkins system of care also provides patient access to ambulatory care at Johns Hopkins through outpatient radiology, home care, and pharmacy services. Finally this total system of care is informed and guided by Johns Hopkins Health Care, the Johns Hopkins managed care organization, which manages the healthcare of more than 250,000 patients. This unique system of care is summarized in Figure 1 below.

Johns Hopkins Medicine is committed to improving the access and quality care across all of its entities. Johns Hopkins has invested in a multi-year strategy to incorporate a single electronic medical record across the clinical care system. This provides a single repository for clinical records for each patients and a single patient number that will be shared by all entities. This investment will streamline access across Johns Hopkins and will improve the quality and timeliness of clinical documentation for all care providers across Johns Hopkins.

Together, these attributes provide unique value to the Johns Hopkins Academic Proton Center at Sibley which will be the singular proton therapy service that will support the patient population of the entire Johns Hopkins Health System and community. The Proton Therapy Radiation Oncologist will work with Multi-Disciplinary oncology teams across the Johns Hopkins Health System to ensure that proton therapy is an integral treatment modality for the treatment of our cancer patients. With the integration of a singular electronic medical record, patient referrals to the proton therapy center will be streamlined and the communication of clinical information will be directly accessible in real time to all Johns Hopkins providers. In addition, a patient's care following proton therapy treatment will be efficiently transferred back to the primary care team. The Johns Hopkins System of Care is well positioned to ensure the success of the Johns Hopkins comprehensive cancer programming, and it is well positioned to provide our healthcare community with the most

Figure 1: The Johns Hopkins System of Care



The Proton Facility staff and physicians are accessed via:

- Physicians within the Johns Hopkins family familiar with the uses of Proton Therapy
- Physicians who are familiar with Proton, but may not be within the Johns Hopkins facilities but may be closely affiliated or aligned (Children's National Medical Center, Anne Arundel Medical Center, Howard University Hospital, All Children's, etc)
- Community physicians outside of the Sibley/Johns Hopkins medical staff who are familiar and want Proton treatment for their patients
- Upon the request of another physician involved in the patients care.
- Word of mouth from existing patients.
- Physicians are listed as providers with insurance companies on whose panels they participate.

Physicians who are employed by Sibley, Johns Hopkins School of Medicine, or Johns Hopkins Community Physicians do not discriminate against any individual on the basis of

race, religion, sex, sexual preference, or handicap. All services are available regardless of a patient's ability to pay, source of payment, or the institutional affiliation of the patient's physician.

Physical Access to the Proton Facility by patients:
The proton facility is located on the campus of Sibley Memorial Hospital at 5255 Loughboro Road. Sibley is fully ADA compliant as will be the proposed Proton. The offices are accessible by car either directly from the garage or at convenient drop-off location at the front entrance of building

Sibley Hospital is also served by the D6 and M4 Metro bus routes. The D6 route connects with Metrorail at Stadium Armory, Union Station, Metro Center, Farragut Square and Dupont Circle in downtown Washington. The M4 connects with the Tenleytown Metro. A Sibley-sponsored shuttle bus service is available to patients, visitors, and staff to and from the Tenleytown Metro Station, running 6 am - 6 pm Monday through Friday. In addition, should a patient need additional care, diagnostic imaging, laboratory tests, or other hospital related services are available on site.

Physician access to Proton Facility:
The Proton Site is on the Sibley campus. All physicians who have privileges at Sibley have access by virtue of their relationship with Sibley.

Partnerships
Sibley/JHM has forged relationships with Children's National Medical Center and Howard University Hospital. Both relationships will include allowing significant access of the Proton Therapy modality to the patients of both hospitals. As further discussed in question 61, these relationships allow for the teaching and training of professional and physician staff. Additionally, we expect that these relationships will open research protocols to these institutions, and all interested institutions to treat tumors with cutting edge cancer research using Proton.

56. State the relationship of your proposed service to existing similar or related services provided by you or others and its impact on these services with respect to utilization, cost and resources (staff). Further, please list all providers of similar services in the proposed service area and/or surrounding service area and the degree to which their service and equipment are being used to capacity. Note that these data may be available in the State Health Plan or from SHPDA staff. Discuss competition in the supply of any service(s) proposed and any ways in which this proposal would foster competition in the financing or delivery of health care.

Response:
Proton therapy does not exist in the Washington, D.C. market. The closest proton therapy centers are located in Philadelphia, PA, which is 150 miles north, or Hampton, VA, which is 180 miles south. As discussed in question 51, there is a significant need in the Washington, D.C. market and in the Primary Service Area for proton therapy. In considering the Washington, D.C. Market,

1. Proton therapy is not provided;
2. There is a real time need for 6 treatment rooms;
3. This need is projected to growth significantly over the next ten years as per the Sg2 report.

The Johns Hopkins Academic Proton Center at Sibley will serve the Cancer Community with the capacity of four treatment rooms. Through its partnerships and research collaborations, the Johns Hopkins Physician and Physics Faculty will work with Sumitomo and other Academic Proton Therapy Center partners to study new care models that will improve treatment efficiency and will increase the capacity of the Proton Center at Sibley.

Proton Therapy is a complimentary modality of Radiation Oncology that can be used for the treatment of Adult Cancers and Pediatric Cancers. Using the Medicare reimbursement guidelines, the indications for clinical use of proton therapy is for tumors of the Central Nervous System, the Eye, the Pituitary, the Base of the Skull or Axial Skeleton, the Head and Neck, and the Lung, for sarcomas, and for pediatric solid tumors. Prostate cancer is indicated on a case by case basis. Please see the Local Coverage Determination (LCD) for Proton Therapy - **Appendix 56**. Through clinical trials, the study of proton therapy use continues to expand and includes protocols for other types of cancer that are not detailed in the Medicare LCD, such as pancreas cancer, liver cancer, and breast cancer.

Proton therapy can be utilized in the treatment of cancer in a variety of ways, which is why it is critical that the development of comprehensive treatment plans utilizing proton therapy is conducted in a Multi-Disciplinary setting. At Johns Hopkins these Multi-Disciplinary Tumor Boards and Clinics facilitate collaborative treatment planning between Medical Oncologists, Surgical Oncologists, Radiation Oncologists, Radiologists, and Pathologists, where real time comprehensive treatment planning and clinical trial assessment is provided to each patient. The Multi-Disciplinary approach established at Johns Hopkins will be the foundation for determining the best utilization of proton therapy when developing comprehensive treatment plans at Sibley. In combination with Multi-Disciplinary Clinics and Tumor Boards, the Johns Hopkins Academic Proton Center will utilize Proton Rounds, which is a best practice that was established at MGH, where the Proton Therapy clinical team discusses each potential proton therapy patient to determine how best to treat a patient with proton therapy, what clinical trials are available for the patient, and what is the best proton therapy treatment protocol. The resulting treatment plans from the combination of Multi-Disciplinary Conferences and Proton Round can include the utilization of proton therapy as the singular intervention, the utilization of proton therapy in combination with conventional X-Ray radiation therapy, or most likely the utilization of proton therapy as part of a multi-faceted approach in combination with surgery and medical oncology.

Though proton therapy may take the place of radiation therapy as the standard of care for certain cancers, proton therapy is a modality that will enhance the treatment options that are available for patients. With the unique ability to control dose allowing for better targeting to the tumor and better sparing of healthy tissue, the use of proton therapy in coordinated cancer treatment plans can result in higher quality and more effective cancer care.

57. Describe the alternative methods (different equipment, floor plans, shared services, etc.) that have been explored, and explain how it was determined that

the project as submitted represents the least costly and/or most effective method to provide the service in question. If the total project cost is > $2 million, attach a copy of reports concerning alternatives studied in terms of service to be provided, budget impact, cost effectiveness, etc. Compare the cost effectiveness of the selected alternative to the "do nothing" option.

Response:
Please see separate binder for response detail

58. Are there ancillary or support services existing to which the project relates or will relate? If so, please describe the expected relationship.

Response:

Proton therapy is usually additive therapy to standard radiation oncology treatments. Routinely, when proton is available, these modalities work in conjunction with one another to treat the patient with increased success. Included in **Appendix 58A** is a flowchart of a patient protocols for Proton Therapy. This flowchart outlines additional services, as well as ancillary and support services that will be used by patients treated on proton depending on the disease diagnosis. The following provides a more detailed description of the plans for Pediatric Radiation Oncology.

Pediatric Radiation Oncology:
Sibley Memorial Hospital (SMH) and Johns Hopkins University (JHU) are partnering with Children's National Medical Center (CNMC) to improve the comprehensive Oncology Care that will be provided to the pediatric patients and their families in Washington, D.C.. SMH, JHU, and CNMC will use their resources to provide new Pediatric Radiation Oncology Services at Sibley, including pediatric radiation therapy and proton therapy. The following collaborative programs are included in the partnership.

- JHU and CNMC will jointly recruit a sub-specialty trained pediatric radiation oncologist who will provide clinical services at SMH and CNMC.
- SMH, JHU, and CNMC will collaborate in the development of a pediatric radiation therapy program which includes dedicated patient navigation, a pediatric anesthesia program and infrastructure, and a pediatric trained nursing team. Pediatric Anesthesia is critical component of the program because 30-40% of pediatric patients will require anesthesia during treatment.
- SMH, JHU, and CNMC will collaborate in the development of the Pediatric Proton Therapy service at the Sibley Proton Therapy Center, which will be a natural extension of the Pediatric Radiation Oncology Program
- JHU and CNMC will collaborate in Pediatric Oncology research, for which the faculty of both Institution are leaders in the international research community, and in the training of Pediatric Oncologists.

In additional to clinical ancillary services, Clinical Trail Research services will be integral to the Sibley Proton Therapy Center. The clinical trial goals of the Proton Center are to develop a robust inventory of clinical trials that is specific to each cancer site and to evaluate each proton therapy patient for clinical trial eligibility. The achievement of this goal

will require significant integration of the Sibley clinical trial research infrastructure with the JHU and the Sidney Kimmel Comprehensive Cancer Center clinical trial infrastructures. Sibley and Johns Hopkins have already made significant progress in advancement including the adoption of the JHU Internal Review Board, through the integration of research leadership under Dr. Theodore Abraham, the Associate Dean for Research in the National Capital Region, and the integration of radiation oncology information systems. The staffing for the Sibley Proton Therapy Center includes clinical trial support analysts and research nurses, as well as the capability for infrastructure growth.

Other Sibley support services, including but not limited to housekeeping, laundry, medical supply, laboratory, pharmacy, diagnostic imaging, dietary, medical records, and infection control will continue to be provided as they are currently at Sibley.

59. Discuss this proposal in relation to the special needs and circumstances, if any, of health maintenance organizations.

Response:

There are no special needs or circumstances of health maintenance organizations which should be considered in relation to this project.

60. Discuss this proposal in relation to the special needs and circumstances, if any, of biomedical and behavioral research projects designed to meet a national need but for which local conditions offer special advantages.

Response:
At Johns Hopkins, the foundation of the tripartite mission has lead to transformative discoveries that have directly benefited the patients at Johns Hopkins and the global healthcare community at large. These discoveries include the first protocolized use of rubber gloves in surgery, to the development of renal dialysis, to the recent discovery of restriction enzymes, which provided the basis for molecular biology and molecular medicine of today. The Department of Radiation Oncology Scientists and Clinicians continue to demonstrate the value of the tripartite mission by taking new discoveries from the lab and bringing them to the clinic for the treatment of patients. A few examples include:

- First to target radiation to tumors using antibodies.
- First to develop and treat patients with prostate cancer with tissue specific viruses.
- First to develop and clinically translate a non-invasive immobilization for stereotactic radiosurgery.
- First to demonstrate the value of PARP inhibitors and radiation for the treatment of cancer.
- First to study, apply, and publish scientific based research on Patient Safety within the context of complex Radiation Oncology workflows.

By aligning the goals of the Academic Proton Center at Sibley with the Johns Hopkins Tripartite Mission, JHM Radiation Oncology and Sibley are committing to continue the tradition of discovery, generating new knowledge that ensures the most contemporary care

of patients and provides the most contemporary environment in which to educate the future leaders in oncology. Committing to advance proton therapy in this way ensures that Johns Hopkins will lead in demonstrating the appropriate use of proton therapy in the treatment of patients with cancer.

There are several opportunities to expand the proven history of the Johns Hopkins Department of Radiation Oncology's ability to take biomedical research and apply it to proton therapy. Using the established infrastructure of the Department's Molecular Radiation Sciences division, Johns Hopkins has a distinct advantage in supporting these important research efforts. The opportunities can be categorized into technological development and translational research.

Technological Development: The Johns Hopkins Academic Proton Center has a unique opportunity to combine the expertise of the Johns Hopkins Chief of Medical Physics, who is the inventor of several technological advances in radiation therapy such as onboard cone beam CT imaging and Active Breathing Motion tumor tracking, and the expertise of the scientist at Sumitomo to develop several advances in proton therapy. One distinct opportunity is to develop one the first robust onboard cone beam CT technologies for proton therapy that will be used for tumor location and treatment quality assurance. This can be taken one step further in the development of unique onboard positron imaging so that proton therapy clinicians can track the dose depth of the proton beam within the body, thus verifying the accuracy of treatment and improving treatment quality. Another distinct opportunity is to utilize non-ionizing radiation sources to track tumor motion and utilize these data in the real time treatment of patient to improve treatment accuracy and quality.

Translational Research: As discussed above, the Johns Hopkins Department of Radiation oncology has pioneered the use of targeting agents such as antibodies and viruses for the delivery of treatment. Because of the precise ability to control the distribution of dose using proton therapy, there are several applications that can be studied for combining these targeting agent treatments with proton therapy. These studies would be conducted as clinical trials at the Johns Hopkins proton center, and they may result in a more effective and a higher quality comprehensive treatment plan for the patient. Another opportunity in utilizing the Johns Hopkins Molecular Radiation Science Faculty in proton therapy is to study the biological effect of high dose proton therapy. This laboratory research can then be translated in the clinical trial based research for high does, short fraction proton therapy treatment. The overall impact would be that patients may be able to receive effective proton therapy in a shorter period of time, for example reducing a treatment protocol from 30 treatments to 15 treatments, thus improving the quality of life for patients and potentially reducing the cost of proton therapy care.

Johns Hopkins has the unique ability to combine the research expertise of its Multi-Disciplinary Oncology Faculty, their long standing research relationship with the National Institute of Health, the research expertise of strategic proton therapy partners, , and the Academic Proton Therapy Center located at Sibley and to develop new translational research collaborations in the advancement of proton therapy. These research opportunities all focus on the improvement of cancer care with proton therapy, which will provide the Washington, D.C. community and the broader proton therapy community with potentially higher quality and more effective treatment options for cancer patients.

61. Discuss the effect, if any, of the means proposed for the delivery of health services or the clinical need of health professional training programs.

Response:
As stated in Question 60, the Academic Proton Center at Sibley will be fully aligned with the Johns Hopkins Tripartite mission, where Education is one of the three core missions. The Education Mission will be implemented through the following programs.

Johns Hopkins University Residency Program: The Department of Radiation Oncology manages an accredited residency program that currently includes twelve slots. The Residency Program is recognized as one of the top programs in the county for the training of residents in radiation oncology and placing residency graduates in top Academic programs across the country. The Academic Proton Therapy program at Sibley, in combination with the Radiation Oncology Center at Sibley and the Medical Oncology Center at Sibley, will provide our Radiation Therapy with a new and unique opportunity to receive training in proton therapy, which will include the multi-disciplinary application of proton therapy in the treatment of cancer and the study of proton therapy in translational research and comparative effectiveness research. It is planned that the JHU Radiation Oncology residents will rotate to the Academic Proton Center as Sibley. It is also contemplated that JHU will apply for the expansion of this program.

Johns Hopkins University Physics Residency Program: The Department of Radiation Oncology, under the leadership of our Chief of Physics, manages a physics residency program. New regulations have been established in that requires the completion of a medical physics resident program in order to receive Board Certification. JHU currently trains 3 residents annually. It is planned that the current physics resides would rotate for training at the Academic Proton Therapy Center at Sibley, and it is contemplated that JHU will expand this program with the start of Proton Therapy.

Strategic Partnership Training Programs: The strategic partnerships with Children's National Medical Center, Howard University Hospital, and other Academic partners to be established have a specified focus on training. This would include their clinicians actively participating in tumor boards, multi-disciplinary education programs, and clinical observerships at the Academic Proton Center at Sibley. The goal of these training opportunities is to broaden the education of the oncology community on the clinical use of proton therapy and the research opportunities with proton therapy. In addition, there are specific discussions with Howard University (HU), American University (AU), and JHU for the development of a unique Medical Physics training that would be the first of its kind in the Region. The program is currently contemplated in two phases. In Phase 1, JHU Medical Physics would collaborate with HU and AU Physics undergraduates and graduates by mentoring these student to provide an exposure to proton therapy and to provide opportunities to work on proton therapy research projects. In Phase 2, JHU, HU, and AU would collaborate in developing an accredited, degree granting graduate training program in Medical Physics where the Academic Proton Center at Sibley and the Radiation Therapy Center at Sibley would serve as the learning lab for these graduate students.

Development of a Training Center: The strategic partnership with Sumitomo includes a collaboration to develop a proton therapy training center at the Academic Proton Center at Sibley. The Training Center is projected to be used for multiple applications. First, it will serve as a training center to support the growth in demand for proton therapy clinicians due to the expansion of proton therapy within the US.
Second, it will serve as a global training site for Sumitomo's clinical partners. Finally, it can serve as a global training site to support the growth in proton therapy in international markets. Training of clinicians in proton therapy is contemplated to be a multi-week program that will require trainees to be on-site at the Academic Proton Center at Sibley and actively participating in clinical education and research education.

In conclusion, Johns Hopkins is committed to the training and education of future leaders in Medicine and more specifically in Oncology. In the 2007 Journal of Oncology Practice article *Future Supply and Demand for Oncologists* – **Appendix 61**, the economic study of supply and demand of oncology services indicated that through 2020 the demand for oncology services will grow 48%, but the supply of oncology services will only grow by 14%. This supply deficit translates to unmet demand for 9.4 to 15.0 million oncology visits or 2,550 to 4,080 oncologists. These gaps in supply present significant issues for the cancer community and the patients who will be seeking care. John's Hopkins and Sibley are committed to dedicate long term training resources at the Academic Proton Center in order to respond to these projected economic gaps in cancer care and to improve the access to Oncology care for the growing community need. The training programs at the Proton Center will start those described above and will have the capacity to explore other opportunities, such as collaborations with local radiation therapy and medical dosimetry schools. These mission based goals for oncology education provides the Washington, D.C. and the broader oncology industry an opportunity to enhance and grow the Oncology training, thus improving the knowledge base of the new Oncology Leaders that will serve the local and broader Oncology communities.

62. If the proposed health services are available only at a limited number of facilities, discuss the extent to which health professional schools in the area will have access to the proposed services for training purposes.

Response:
Johns Hopkins and Sibley are committed to the mission of improving education in Oncology Care and in Proton Therapy. Johns Hopkins and Sibley are working with Strategic partners to develop Training Capacity at the Johns Hopkins Academic Proton Center. This training capacity will support the needs of Johns Hopkins, the needs of Strategic Partners, the local health professional programs in Washington, D.C., and other domestic and international training program needs. More specifically, as is currently provided at Johns Hopkins Hospital, Sibley and Johns Hopkins will work with Washington, D.C. or other local radiation therapy schools and dosimetry schools to provide exposure and training to radiation oncology and proton therapy. For more specific details on the planned training programs for the Johns Hopkins Academic Proton Center at Sibley, please see the Response to Question 61.

63. If you claim to be an entity which provides a substantial portion of your services or resources, or both, to individuals not residing in the Washington Metropolitan Area, discuss your special needs and circumstances in relation to this project.

Response:
Usually, Sibley describes its service area as those zip codes from which Sibley receives 75% of our inpatient and outpatient patients. However, given the regional nature of this service, and the fact that the nearest proton centers are over 150 miles away, it is our expectation that we will draw from a much larger service area. Usually, Sibley sees patients from D.C., Maryland, and Virginia, with only 2.7% of our patients coming from outside these contiguous jurisdictions. However, based on research and experience of other proton centers, it is expected that Sibley will draw from a larger service area which extends out at least 100 mile radius (see service area map in exhibit 22). We also anticipate, based on information from other Proton Centers, as well as the District of Columbia being an international city, that approximately 7-10% of Proton patients will come from outside the United States.

It is expected that the patient population coming in from outside the Washington Metropolitan region will require help in coordination of care as well as basic help with logistics. The collaborative Sibley-Johns Hopkins International Department is located in Sibley's new Medical Building. The goal of this department is to facilitate access to clinical services at Sibley Memorial Hospital and to coordinate the logistical demands of patients who are traveling from outside the regions to access these services at Sibley. The Department will be developed in coordination with the established and growing Johns Hopkins International Department located at the Johns Hopkins Hospital. The coordination of clinical services include the following:

- Each patient from outside the area is assigned a "medical concierge" who assists with any transportation and accommodation needs related to patient visits.
- Helpful, knowledgeable financial counselors assist with preparing estimates, understanding the bill, providing payments, verifying insurance or embassy coverage and delivering a convenient final bill within 90 days of visits.
- Patients will receive a packet outlining appointment details and the estimated cost of scheduled services. The medical concierge will confirm appointments shortly after patient medical records are received. The office will then send a packet with the physician name, the time, date and location of all appointments, and other important information.

Economic Potential for D.C.

We expect that the patients coming from outside the region will add to the District economy through utilization of hotels, restaurants and other services within the District. Sibley has a number of hotels with which it has special rates to provide patients and families in need of lodging a place to stay.

Additionally, the project development as well as ongoing operations of the Proton Center, and associated training facility will be very beneficial to the District of Columbia.

While there appears to be no single study or formula for calculating the economic impact of proton therapy centers, multiple project applicants in other regions have outlined the anticipated benefits:

- Immediate construction jobs;
- Ongoing new positions with higher than average salaries (see response to question 43A in Section 1.
- Hospitality revenue from patients and their families who travel to the region for care.

Examples from other projects include:

- The Mayo Clinic is Scottsdale, Arizona expected to draw over 100,000 medical "tourists" to their 100,000 square foot facility annually after it opens in 2016.
- Officials in Knoxville, TN were told to expect $30 million in annual impacts for their 3-room treatment center with 700 annual patient visits.
- The Village of Wellington in Palm Beach County, FL estimated the impact of a 60,000 square foot proton therapy center at over $240,000,000 in its first year of operation, exclusive of certain tax revenue that would not be assessed against a not-for-profit facility. Most of the benefit is derived from salaries and the multiplier effect of the spending by those workers in the regional economy.

Other local officials have accepted the case and made economic development grants or offered other incentives in multiple jurisdictions, including i.e. Dallas-Ft. Worth, Dayton, Jacksonville.

64. What would be the economic impact on the facility if the proposed project were not implemented?

Response:

If Sibley were not approved the Certificate of Need for the development of an Academic Proton Center, there would be several impacts, and unfortunately the patient community would be the ones most impacted.

First, there is a direct impact on patient care. In referencing the response to Question 48, several key points were established.

1. Scientific research has shown that for pediatric solid tumors, tumors of the eye, tumors of the brain, tumors of the head and neck, chordomas, scarcomas, and other solid tumor sites, proton therapies are superior to X-Ray based IMRT.
2. Scientific research has preliminarily shown that treatment with protons lowers the risk of secondary cancer in children and adults.
3. Using published population and cancer incident rate data, there is a significant need in the Washington, D.C. market for proton therapy.
4. The Johns Hopkins Academic Proton Center is planned to treat nearly 1,000 patients annually, yet there will still be excess demand in the market.

If the Sibley Proton Therapy Center is not approved, then the need in the Washington, D.C. market will be un-served by the Market's healthcare system, as there are no current local

providers of proton therapy. This will require patients to travel out of the region to access services, often requiring the patient and family to relocate for 4-6 weeks to obtain these services. The economic requirement of this extended relocation will serve as a barrier to proton therapy care for a significant portion of Washington, D.C. Market population, and though the therapy may be safer, may be more effective, may be needed, and may be demanded, the therapy will not be accessible.

Second, in the planning for the Academic Proton Center, Johns Hopkins and Sibley will be investing significant resource to develop incremental clinical oncology programming associated with proton therapy that will enhance Oncology Care in the Washington, D.C. market.

1. The development of a unique and comprehensive Pediatric Radiation Oncology Program where radiation therapy services and an entire proton therapy treatment room are devoted to the treatment of children with cancer. Johns Hopkins, Sibley, and Children's National Medical Center will form a strategic partnership in this Pediatric Radiation Oncology Program to enhance pediatric cancer care in the Washington, D.C. market.
2. The development of a unique Proton Therapy Clinical Trial Program, where Multi-Disciplinary Teams of physicians from Johns Hopkins and our Strategic Partners will collaborate to provide new and innovative therapies to the Washington, D.C. Market for the treatment of cancer.
3. The development of a unique Proton Therapy Technical Research Program, where Johns Hopkins faculty and scientist will collaborate with our Strategic Vendor Partner scientists to advance proton therapy technology by enhancing quality, safety, efficiency, and capability.

If the Sibley Proton Therapy Center is not approved, then the cancer community in the Washington, D.C. Market will not have local access to comprehensive Pediatric Radiation Oncology, innovative clinical research, and new discoveries in proton therapy discussed in the above programming. Again, patients will have to travel outside of the region to receive these types of Oncology services and Programs.

Third, in the planning for the Academic Proton Center, Johns Hopkins and Sibley are planning to invest significant resources in the development of training programs, as discussed in response to Question 61.

1. Development of Physician and Physics residency programs at the Sibley Proton Therapy Center. These residency programs are critical in training our future leaders in Medicine in advanced therapies and proton therapy research.
2. Development of unique Medical Physics Research Programs with Howard University and American University, where Johns Hopkins collaborates with these Strategic Partners to help expose graduate and undergraduate students to the field of Medical Physics. Long term planning could include the development of a Graduate Training Program in Washington, D.C.
3. Development of a Proton Therapy training center in collaboration with Sumitomo that will serve as a global training site to address the growing demand for clinical training in Proton Therapy as the numbers of proton centers continue to grow across the global market.
4. Partnering with local radiation therapy and medical dosimetry schools to provide exposure and training in proton therapy and radiation therapy.

If the Sibley Proton Therapy Center is not approved, then these unique opportunities to provide contemporary training programs in proton therapy and medical physics in Washington, D.C. will not be possible. Because proton therapy training programs and medical physics training programs are a limited resource in the US and because there is no local access to proton therapy or medical physics training programs, the ability for Physicians, clinical providers, undergraduate, and graduate students in the Washington, D.C. Market to access these training programs will be limited.

Fourth when Sibley and Johns Hopkins entered into their Strategic Partnership, both Sibley and Johns Hopkins initiated the strategic goal of enhancing Oncology Services at Sibley Hospital for the Washington, D.C. community. Definitive actions have already been implemented and/or are in process.

1. The new Radiation Oncology Department was development and opened in a collaborative effort between Sibley and Johns Hopkins.
2. In another collaborative effort, a new Infusion Center was constructed and opened by Sibley in the Professional Office Building, and it is managed by John Hopkins University Medical Oncologists.
3. The planning for the New Sibley Hospital includes designated space for the enhancement and expansion of medical oncology services.

The investment in Proton Therapy is another collaborative effort by Sibley and Johns Hopkins to develop new and innovative oncology programming at Sibley. As discussed in Part 1 of the application and as approved by the Johns Hopkins Medicine Board of Trustees Facilities and Real Estate Development Committee, Debt Sub-Finance Committee, and Finance Committee, significant capital resources are being committed, are being raised through philanthropy, and/or are being guaranteed by Johns Hopkins for this investment in oncology services at Sibley and in Washington, D.C.. If the Johns Hopkins Proton Center is not approved, then the investment for this enhancement of oncology services, including the incremental Education and Research programs will not occur.

Finally, as mentioned earlier in question 63, the potential economic gain to the District of Columbia is great. If this proton project is not approved, the District would not gain by all that is outlined above.

65. What reviews, approvals, licenses, etc. are required by other governmental agencies for the implementation and operation of this project?

Response:

The project will require a building permit from the D.C. government. The D.C. Department of Environment will need to approve the submission of an Environmental Impact Statement Form.

Prior to operation, a review and approval will also be required by the Services and Facilities Administration of the D.C. Department of Health. The shielding design and final radiation calculations will also be reviewed and approved by the D.C. Department of Health, Radiation Protection Division.

66. Discuss accessibility in relation to the proposed project in terms of the following:
    a. transportation patterns and resources for patients and visitors;
    b. hours and range of services provided;
    c. barriers to obtaining services (physical, cultural, economic); and
    d. physician referral and/or admitting patterns (if discussed in 55).

Response:

a. Sibley Memorial Hospital is located in the far northwest corner of the District. Sibley is well served by Metrobus and Ride-On. Additionally, with the opening of the Sibley Medical Building, a shuttle runs from the Tenleytown Metro Station, providing service to employees, visitors, patients, and community members wishing to use this form of transit to our campus. Over the past few years, Sibley has made significant efforts to develop new strategies that will improve the vehicular and transit accessibility to Sibley, while minimizing impacts on the surrounding community. These strategies include:
    1. Reconfiguring of the Dalecarlia Parkway and Loughboro Road intersection and a new vehicular entrance off Dalecarlia Parkway
    2. Shuttle bus service to Friendship Heights Metro station
    3. Programs to incentivize transit use and carpools
    4. Priority parking for low-emitting and alternative fuel vehicles

b. The Sibley Proton Therapy Center will be open Monday through Friday 13 hours per day once it is fully in operation. Additional capacity will be available with weekend and extended weekday hours as demand grows.

c. The Proton Therapy Center will not affect Sibley Memorial Hospital's long-standing commitment to provide services regardless of patient cultural or economic conditions. All patient areas of the Hospital are fully accessible to the handicapped, and this will be true of the new Proton Therapy Center as well.

   Sibley Memorial Hospital does not discriminate against any individual on the basis of race, religion, sex, sexual preference, or handicap. Sibley makes all of its services available regardless of a patient's ability to pay, source of payment, or the institutional affiliation of the patient's physician. The same will continue to hold true after we complete the proposed Proton Therapy Center.

   Additionally, with the close partnership being forged with Children's National Medical Center (CNMC), pediatric patients who usually access CNMC will have seamless transition to the Sibley Proton Therapy Center for pediatric radiation oncology services, including Proton Therapy, thus allowing greater access to patients who may not normally be aware of Sibley's services. We are also forging a partnership with Howard University Hospital. This relationship will also improve access to services at Sibley for patients who may not be aware of Sibley's services or who may not typically have access them in the past. At Proton Therapy is a scarce resource at this time, and not available elsewhere in the Washington, D.C. area, we are committed to reaching out beyond Sibley's usual patient base to make this life-preserving treatment available to all.

d. For a description of the referral process to Sibley's Proton Therapy Center, please see the response to question 55, above.

67. Describe the potential, if any, which the proposed service offers for a reduction in the use of inpatient care in the community, e.g., through alternatives to institutionalization or services of a preventative nature.

Response:

Proton Therapy, like radiation therapy, is primarily an outpatient service, in which 95% of care will be performed as outpatient care. Proton therapy is a concurrent cancer therapy that is often integrated with multimodality care plans. There may be a need to provide proton therapy services to a cancer patient who is admitted as an inpatient oncology patient, but this will not reduce the utilization or need for inpatient care in the community. The proposed Proton project is not expected to negatively affect the utilization of inpatient services in the community.

68. Have mechanisms been developed to consider consumer grievances, and to provide for consumer participation and rights. If so specify.

Response:

Sibley Memorial Hospital is committed to providing quality health care which is fully satisfactory to patients, their families, and physicians. Sibley recognizes and supports the Patient's Bill of Rights, as established by the American Hospital Association. The Hospital's policy for investigating and responding to inquiries, concerns and problems or patients or their families is outlined in **Exhibit 68A** (copy of Hospital Policy #03-25-21). Hospital officials are personally available to respond to customer grievances whenever possible. When a customer complaint is received, it is investigated immediately, remedial action is taken as appropriate, and the affected parties are informed of the resolution. These policies will continue to be in practice after the Hospital the new facility. This is also outlined in our Patient Rights Policy included in **Exhibit 68B**, and the Patient Information Guide, included as **Exhibit 68C.**

69. Discuss any transfer or coordination agreements and any other appropriate linkages in the system to provide a continuum of care which are proposed or which have been implemented. (Please attach agreements).

Response:

Sibley Memorial Hospital has established transfer agreements with most of the hospitals in the Washington metropolitan area for regular patient transfers. Appropriate transportation arrangements are made in accordance with the patient's physical and mental condition, and may be provided by the Metropolitan Police Department, the District of Colombia Fire Department, rescue squads, private ambulance companies, or by other vehicular means. A standardized transfer form, utilized by all metropolitan area hospitals, is completed by the appropriate personnel prior to the patient's discharge or transfer to another facility.

Copies of the transfer and coordination agreements as well as Sibley's transfer and referral policies are included in **Exhibit 69** (copy of Hospital Policy 03-31-01).

Additionally, it is expected that patients referred to the Sibley Proton Therapy Center from outside our immediate area, or by one of our partner hospitals, will return to care within those systems. We anticipate communication between the Sibley Proton Therapy Center and Children's and Howard Hospitals to be well established through our institutional agreements. The ideal for patients is to return home after Proton Therapy and to receive any additional necessary treatment in their own community.

If the patients accessing Proton Therapy have come from within the Johns Hopkins System, their care will be coordinated through the use of our system-wide patient information system, Epic. All Hopkins hospitals will be connected through this patient electronic medical record, which will provide seamless transitions of care.

70. State the relationship of the proposed services to the existing health care system in terms of:
    a. community health promotion and prevention;
    b. prevention and detection;
    c. diagnosis and treatment;
    d. rehabilitation;
    e. chronic maintenance;
    f. support services;
    g. enabling services.

Response:

Sibley has been very active in health promotion, prevention, detection, and educational programming, currently offering or participating in a multitude of programs with outreach activities planned throughout the year. These activities include cancer screening and prevention education for non-cancer patients, cancer education for cancer survivors, and survivorship programming for cancer survivors to assure that late effects are treated and secondary cancers are diagnosed early. In addition, there are cancer screening programs for breast cancer, lung cancer (low dose CT screening), and colorectal cancer (colonoscopy). The following are a few examples of community-based programs and activities emphasizing health promotion, disease prevention, and early detection that are currently or will be offered.

- Avon Breast Cancer Walk. Sibley was the medical sponsor of this event in the spring of 2012 with plans for 2013. Sibley also provided Medical Directorship for this weekend long walk and will continue that role in 2012.
- Susan G. Komen for the Cure. Through its active participation in this annual Washington, D.C. event. Sibley's most recent funding in 2010 supported breast navigation, including palliative care needs and access to novel research studies.
- *Knowledge Is Power* community education programs on the topics of ovarian, breast and lung cancers.
- Sibley offers an in-patient consultative palliative care service under the leadership the Director, Hospitalist Service and a nurse practitioner who is board-certified as a Hospice and Palliative Nurse.

- Sibley offers a Clinical Genetics Service with a fellowship trained physician who is board certified as a clinical geneticist.

Sibley has developed a strong clinical research program over the past decade that will become more robust with the influence of School of Medicine faculty researchers through Sibley's affiliation.

- Sibley participated in two prevention studies, the STAR Breast Cancer trial and the SELECT Prostrate Cancer trial which are now closed.
- Sibley is a main member of the Alliance for Clinical Trials and Oncology which requires enrolling 30 patients/year. Sibley is a satellite of Franklin Square Medical Center for studies sponsored by the National Surgical Adjuvant Breast and Bowel Project (NSABP) cooperative group and Walter Reed Army Medical Center for Gynecologic Oncology Group (GOG) cooperative group studies.
- Twenty-two treatment studies are open to accrual at Sibley.
- Sibley enrolls on average 50 patients annually onto phase 2 and phase 3 treatment studies. The majority of studies are sponsored by the National Cancer Institute. Sibley is working with Walter Reed Army Medical Center on a novel breast cancer vaccine study for a specific patient population and was recognized for being the most active civilian community hospital.
- Michael Carducci, MD, Professor of Oncology and Urology at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in Baltimore has enrolled two patients onto one of his metastatic prostate studies. This is the first cohort of local patients to benefit from access to Hopkins research as a result of the affiliation with Hopkins.
- 254 patients enrolled in a clinical research study have completed active treatment and participate in long-term follow-up.

In addition, there are many support services at Sibley directed at current and past cancer patients and their families, including these examples.

- Resource Center. The outpatient facility scheduled to open October of 2002 will include a resource center that is easily accessible to patient, family members and friends. This room will include Internet access for patients to access Internet based resources, as well as a wealth of journals and books. This space will compliment Sibley's current inpatient oncology resource center located within the hospital.
- "Look Good Feel Better." Sibley has participated with this American Cancer society program since its inception in 1989. This program helps patients overcome the barriers of some side effects of treatment, providing cosmetics and accessories.

In light of the fast-paced changes taking place in oncology services at Sibley, and the possibility of access to new ideas and resources after the Sibley/JHM integration, Sibley has engaged a consultant to assist us in a process to inventory regional programs, including survivorship resources and programming currently in place at the Johns Hopkins hospitals and the local community. Based on the findings, we will develop a plan to take advantage of synergies across the system and develop a coordinated program across the hospitals that meets the needs of each community. This effort will strengthen and expand our current support services and benefit all Sibley oncology patients, including Proton Therapy patients.

Proton therapy patients who are referred from other hospitals and distant jurisdictions may prefer to receive rehabilitation services at their "home" hospital. For the patients for whom Sibley is their regular site of care, or who simply prefer to continue in care at Sibley, the Sibley Center for Rehabilitation Medicine is available to provide services to cancer patients with all diagnoses. Rehabilitation services available include:

- Lymphedema prevention, education and management
- Strength, range of motion and functional restoration
- Manual therapy for soft tissue mobility and joint mobility
- Posture education
- Return to exercise and lifestyle
- Sport specific and activity specific exercises
- Fitness programs
- Patient Education
- Pelvic Floor treatment

Diagnosis and staging of a patient's cancer is typically done prior to being referred to a Radiation Oncologist. At Johns Hopkins SKCCC, a cancer patient's diagnosis and tumor staging is rigorously evaluated in a multi-disciplinary setting to ensure the accuracy of the clinical evaluation and the accuracy of the patient-specific treatment plan to be developed. During this evaluation, Medical Oncologists, Radiation Oncologists, Surgical Oncologists, Radiologists, and Pathologists collaborate to develop the optimal treatment, management, and follow-up plan for each patient. For patients who will be referred for proton therapy treatment and who will receive treatment, Figure 1 below illustrates the expected clinical pathway that will be followed over the course of diagnosis and treatment for a proton therapy patient and shows the relationship of proton therapy to the existing oncology and related services.

For examples of some of our outreach and education materials, please see **Appendix 70**

71. Discuss the quality of any care currently provided (if any) and the care proposed to be provided. The following points should be described and quality demonstrated:
    a. organization and management;
    b. certification and licensure;
    c. medical direction;
    d. staffing;
    e. peer review, utilization review, medical audits;
    f. continuing education for staff.

Response:

The following responses support Sibley Memorial's current commitment to providing quality care, a commitment which will continue and which will be enhanced as we plan and develop the Sibley Proton Center. We fully anticipate that the Proton Therapy Project will elevate our established history of providing high quality of care. This elevation will be possible for the following reasons.

1. We will provide our patients with a technology that is proven to reduce adverse radiation toxicity to patients.

2. We will extend the access of this technology to the pediatric and adult cancer community in Washington, D.C., and this access will be facilitated and enhance through our partnerships with Howard University Hospital, Children's National Medical Center, and other Healthcare Providers in the District of Columbia and the broader region.
3. We will be able to actively participate in the Radiation Oncology Safety research that is pioneered by the Johns Hopkins University Faculty.
4. We will be able to integrate with the Johns Hopkins Armstrong Institute that is led by Dr. Peter Pronovost, a global leader in healthcare safety..
5. We will directly collaborate with the extensive research infrastructure of the Sidney Kimmel Comprehensive Cancer Center and the Johns Hopkins University to provide new and innovative clinical trials to the Washington, D.C. community.

Sibley Memorial Hospital has a formal Patient Safety and Quality Coordination Department. Resources include Occurrence reporting System, Root Cause Analyses, Failure Modes and Effects Analysis, Infection Control, Invasive Procedure Review, and Utilization Review. In the area of oncology, Sibley will be moving toward full integration with Johns Hopkins quality programs. Examples of existing Johns Hopkins Quality Management Programs (QPMs) can be found in **Appendix 71A in the separate binder**

Sibley Memorial Hospital, Johns Hopkins University, and Johns Hopkins Health System have been actively collaborating to integrate their Radiation Oncology Programs and to Partner in an integrated Proton Therapy Center. The integration was strategically implemented with the goals of enhancing the quality of the Sibley Radiation Oncology Program by standardizing the radiation equipment and information systems between Sibley and John Hopkins, by standardizing the patient information management systems between Sibley and Johns Hopkins, thus enhancing communication and collaboration on multidisciplinary patient care, by enhancing access to new and innovative clinical trials, including advanced non-radiation emitting image guidance and motion management, and by standardizing Radiation Oncology specific quality and safety programs between Sibley and Johns Hopkins. The following list documents that collaborations that have already been completed and are in process to accomplish these goals. Relevant CVs are included in **Appendices 71B – G.**

- Sibley Department Leadership is integrated under Dr. Theodore DeWeese, Chairman and Professor, Department of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine.
- Sibley Medical Physics Leadership is integrated under Dr. John Wong, Chief of Medical Physics and Professor, Department of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine.
- Sibley Oncology Leadership is integrated under Dr. Irene Gage, Medical Director and Associate Professor for Oncology Services in the Johns Hopkins National Capital Region.
- Sibley radiation oncology equipment and information systems at Sibley are integrated with Johns Hopkins.
- Sibley clinical trial research infrastructure and Internal Review Board is integrated with Johns Hopkins University.
- Safety and Quality programming and research is integrated with Johns Hopkins.

- The first quality and safety research project collaboration between Sibley and Johns Hopkins was completed which applied a Failure Mode and Effective Analysis study to the complex operational workflow of Sibley Radiation Oncology.
- Sibley has integrated with the propriety Johns Hopkins University Radiation Oncology safety and quality reporting system.

- Next Steps:
  - Integrate the Sibley Radiation Oncology quality management with the Johns Hopkins University Quality Management Program (QMP) for Radiation Oncology. The Johns Hopkins QMP is attached. All QMPs are included in **Appendix 71A** which is found in the separate binder
  - Integrate the Sibley Electronic Medical Record (EMR) with Johns Hopkins Health System investment in the EPIC EMR.
  - Complete a collaborative Radiation Oncology Certification through the American College of Radiology. The Certification will include Johns Hopkins Hospital, Sibley Radiation Oncology, and Johns Hopkins University Radiation Oncology at Suburban.

a. Sibley Memorial Hospital is duly licensed by the government of the District of Columbia as an acute care hospital. The Hospital is also accredited by the Joint Commission on Accreditation of Healthcare Organizations. These approvals indicate that quality of care is provided throughout the entire hospital. Sibley complies with all licensing and regulations that govern the management of live radiation sources and radiation therapy technology in the District of Columbia. As stated above, Sibley will be collaborating with Johns Hopkins to obtain accreditation of the Radiation Oncology program through the American College of Radiology..

c.&e. The Medical Staff of Sibley is organized into clinical departments, each of which operates as a separate section of the Medical Staff and is led by a Chairman who is a member of the Executive Committee of the Medical Staff. Each Chair holds monthly meetings where utilization review and medical audits are presented. Statistics and unusual cases are presented. Re-admissions, are discussed as well as cases with length of stay concerns. Some clinical sections have specific meetings in which 2-4 cases are presented in depth and discussed. The Chairman of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine will be the Medical Director for the Sibley Proton Therapy Center. The Medical Director will report through the Medical Staff structure at Sibley.

Under the Direction of the Medical Director of the Sibley Proton Therapy Center, several peer review programs will be implemented to ensure the highest quality of care for patients. These Peer Review Programs will benchmark the established peer review programs of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center.

- Tumor Boards – In a multidisciplinary setting Radiation Oncologists, Medical Oncologists, and Surgical oncologists will review cancer cases and develop the best cancer care plan for the patient and will evaluate the patient for clinical trial eligibility.
- Multidisciplinary Clinic – As established at Johns Hopkins, these sub-specialty clinics will provide a patient with a comprehensive review of her

disease by a Sub-Specialty trained Radiation Oncologist, Medical Oncologist, Surgical Oncologist, Pathologist, and Radiologist. During this one day visit, the patient will be provided a fully comprehensive care plan that is customize for her disease.

- Proton Peer Review – The Proton Therapy faculty will meet weekly to discuss the potential proton therapy cases and will determine the best comprehensive radiation care plan specific for each patient. During this peer review, clinical trial eligibility will be evaluated for each patient.
- New Patient Peer Review – The Proton Therapy faculty will meet weekly to review the treatment plan for each new patient. This peer review process will ensure that the patient will be receiving the safest and highest quality care proton therapy treatment.
- On Treatment Review – On a weekly basis each patient will have their course of treatment and their medical condition reviewed and evaluated by the Radiation Oncologist and Medical Physics. This ensure the highest quality of treatment is delivered throughout the course of treatment, and this ensures that the patient's evolving response to treatment is continually evaluated and managed.

d: The staffing of the Proton Therapy Center will be conducted to ensure the highest level of safety and quality for our patients. Clinical staffing will be lead by the Medical Director of the Sibley Proton Therapy Center. The following staffing is planned to ensure the highest level of quality and safety for the Sibley Proton Therapy Center Patients.

i. Leadership – The clinical program will be led by Sibley Proton Therapy Center Medical Director. Medical Physics and Medical Dosimetry will be led by the Johns Hopkins Medicine Chief of Medical Physics. The Proton Center will also have a dedicated Chief Radiation Therapist and a dedicated Nurse Manager.

ii. Radiation Oncologists – The Sibley Proton Therapy Center will be staffed by five radiation oncologist, each of which will have a sub-specialty cancer focus, such as Pediatrics, Central Nervous System, Head and Neck, and Gastrointestinal.

iii. Radiation Therapists – The staffing for radiation therapist will ensure that three radiation therapist will be managing the patient care and administering the proton therapy for each treatment room and the simulations.

iv. Nursing – Nursing support will be provided both in the clinical consultation setting and in the treatment setting. There will be sub-specialty trained Advanced Practice Professionals and nurses to support the care of our adult and pediatric patients.

v. Pediatrics – There will be a sub-specialized team of clinicians to ensure the highest levels of safety and quality for our pediatric patients. The Sibley Proton Therapy Center will have a dedicated team including a Pediatric Anesthesiologist, anesthesia prep and recovery nurses, and anesthesia technicians to ensure the safest care for our pediatric patient who require anesthesia during treatment. The pediatric program will be led by a sub-specialty trained Pediatric Radiation Oncologist, who will be supported by a sub-specialty trained nurse and Advance Practice Professional.

vi. Staffing levels for medical physics and dosimetry will be determined by the Chief of Medical Physics and will comply with industry standards, such as the ASTRO Blue Book. The staffing plan includes a lead clinical physicist, a lead accelerator physicist, and 5 medical physics to support the clinical practice. The plan also includes 5 medical dosimetrists to support the clinical practice.

f. All professional staff are required to participate in continuing education in order to meet and exceed the highest standards of quality. Continuing education activities include seminars and other specialized training. Technical staff also receives regular in-service training. Training for the nursing and technical staff is coordinated by a Clinical Nurse Specialist. Nursing staff of the departments participate in education programs as well as any necessary equipment specific monitoring competency training. Staff is also trained in Basic Life Safety, infant CPR in addition to adult CPR which is included in the Hospital wide training program.

One of the key Missions for the Sibley Proton Therapy Center and for Johns Hopkins is our Education Mission. The following are several programs that will be established to achieve this Mission. Achievement of this Mission will require staff to receive continual education internal peer program and external programs. Many of the Proton Center's staff will also be educators in the achievement of this mission.

- Johns Hopkins Residency Programs – The Johns Hopkins Department of Radiation Oncology currently manages a twelve slot Radiation Oncology residency program and a three slot Medical Physics program. It is planned that both programs will be augmented to support the Sibley Proton Therapy Center and to support the education of our future clinical leaders in proton therapy.
- Partner Education Programs – Through Partnerships with Children's National Medical Center, Howard University Hospital, and other clinical and academic partners, training and research program collaborations will be established to ensure that the local Oncology leaders are trained in proton therapy.
- Medical Physics Programs – Johns Hopkins and Sibley are developing partnership with Howard University and American University to create a unique Medical Physics Training program that will provide the undergraduate and graduate physics students experience and education in the field of Medical Physics.
- Training Center - Through its partnership with Sumitomo, Johns Hopkins and Sibley are collaborating to develop a Training Center at the Sibley Proton Therapy Center that will provide access for clinicians across the country and the world to receive clinical training in proton therapy.

The development of these programs will ensure that the Sibley Proton Therapy Center is able to achieve its Education Mission, and it will also ensure that the Sibley Proton Therapy Center creates an environment where learning that continually elevate the quality and safety of the care provided.

72. Discuss the costs and methods of any proposed construction in this project. Include a discussion of the method of energy provision and the methods used for energy conservation. Discuss the relationship of the selected construction type and method of energy provision to construction costs and future operating

costs. Also discuss the methods used to estimate construction and equipment costs. Attach a copy of any available construction plans or drawings.

Response:

As mentioned in question 2 above, the proton facility will be located on the northwest corner of Sibley's property bounded by Little Falls Road to the north, the existing service drive to the south, the new service drive and ambulance entrance for the New Sibley project to the east and the parking garage to the west. Specifically, it will be sited on the east end of the existing pre-cast parking garage. The footprint is approximately 20,000 square feet and will be accessed by removing the precast "double tees" that currently form the parking deck. Grade will be achieved at the site by removing one layer of double tees.

The facility will be at the west end of the circulation spine that connects to the first floor of the New Sibley. Most of the first floor of the New Sibley will be dedicated to Oncology facilities. To access the proton facility, one would proceed on a short walk westward from the New Sibley Lobby, traversing the medical oncology department and crossing a short bridge over the new service drive.

This site was chosen after a careful study of several possible locations. We chose this one because of its convenient location in relation to the new Oncology facilities. Additionally, locating construction and operation of this facility on the north side of the property minimizes visibility and impact for the neighborhood. The footprint for the building is readily accessible by minor modifications to the existing pre-cast parking structure.

The building estimate was based on historical data assembled from a consultant that has been directly involved in the construction of several Proton Therapy sites across the country. A single gantry system was briefly considered, however, the return on investment and limited capacity did not achieve the goals of Sibley/Johns Hopkins Medicine. At this stage of development, we can only comment on energy savings criteria in that the building design will be based on the green building standards as required by the District of Columbia. Construction methods are poured in place concrete for the vault and treatment areas. The concrete construction is for shielding requirements as well as supporting the mass of the proton therapy equipment. Structural steel fabrication for above-grade mechanical, exam, consult, and support room spaces will be used. The exterior skin would be designed to match the campus, with reviews as appropriate by trustees and the local jurisdiction. Preliminary floor drawings are included in **Appendix 72**.

73. What steps have been taken to inform the Advisory Neighborhood Commission?

Response:

On July 11, 2012, Jerry Price, Greg Sibley, MD and Christine Stuppy were present at the ANC 3D meeting. The Sibley team briefed the ANC and answered questions from ANC council members. The Project was described in detail. See attached letter from Stuart Ross, President of ANC 3D in **Appendix 73**

74. Provide any other available evidence or documentation that the facility, program or service has or will have the support of the health consumers of the area (consumers include representative community organizations, patient groups, etc.) or state that no such evidence is available.

Response:

As stated above in question 48 the proton project is a collaborative effort with many partners. Below is a review of the alliances that have been forged to date. Additionally, there are a number of relationships being explored for which documentation will be forthcoming.

a. *WellSpan Health* – **(See Appendix 74A and 74B)** – WellSpan Health is an integrated health system that includes cancer programming at WellSpan York Hospital and WellSpan Gettysburg Hospital. The WellSpan cancer program provides clinical services to 2,400 new cancer patients annually. WellSpan and Johns Hopkins have had a long-term partnership that includes The Johns Hopkins Hospital as the primary tertiary referral site for WellSpan's cancer patients. Sibley, Johns Hopkins, and WellSpan are formalizing partnership planning that will expand the current relationship to include the Sibley Proton Therapy Center as a referral site for WellSpan's proton therapy patients.

b. *All Children's Hospital* – **(Appendix 74C)** All Children's Hospital is a John Hopkins pediatric hospital located in Tampa, Florida. All Children's Hospital does not have access to proton therapy in Tampa, and patients must be referred to out of area proton therapy centers such as Massachusetts General Hospital, MD Anderson, and University of Florida. All Children's, Sibley, and The Johns Hopkins University School of Medicine have executed a Memorandum of Understanding to develop a Collaborative Program which will provide access to Johns Hopkins proton therapy and tertiary radiation therapy at Sibley through the collaborative multidisciplinary management of cancer patients, and which will establish collaborative research and training programs in pediatric oncology.

c. *Howard University Hospital ("**HUH**")* **(See Appendix 74D)** – Johns Hopkins has had a long standing partnership in Oncology research and training with Howard University. Johns Hopkins, Sibley, and HUH are formalizing a partnership that is founded on this established research relationship and are extending it to include proton therapy. As partners in proton therapy, Sibley Johns Hopkins and HUH will work to develop collaborative programming that provides proton therapy access to HUH cancer patients, that grows current collaborative research to include proton therapy, and that develops training opportunities for Oncologists, Medical Physicists, other clinical professional and undergraduate and graduate students.

d. *Children's National Medical Center ("**CNMC**")* (MOU forthcoming) – Johns Hopkins and Sibley will partner with CNMC to develop a comprehensive pediatric radiation oncology program at Sibley. Sibley CNMC and Johns Hopkins will develop a multi-disciplinary pediatric oncology program that will span campuses and provide the District of Columbia's pediatric oncology patients with access to world class oncology providers, to coordinated pediatric oncology programming under the leadership of

specialty trained pediatric oncologists, and to collaborative clinical trials. CNMC will partner with Sibley to bring proton therapy to the pediatric cancer community in Washington, D.C., the Sibley Proton Project's Primary Services Area and Regional Service Area so that patients and their families will have local access to proton therapy and not have to be displaced from home for weeks at a time while seeking proton therapy care outside of the region.

e. *Walter Reed National Military Medical Center* ("**WRNMMC**") **(See Appendix 74E)** *and The National Cancer Institute* ("**NCI**") – WRNMMC, NCI, and Johns Hopkins have initiated discussions to explore opportunities to develop clinical trial research and laboratory research collaborations in the study of proton therapy at Johns Hopkins and Carbon Therapy at the proposed Carbon Therapy Center at WRNMMC. WRNMMC, NCI, and Johns Hopkins have initiated discussions to explore opportunities to develop a collaborative Medical Physics clinical and research program in proton therapy at Johns Hopkins, and Carbon therapy at WRNMMC.

f. *American University ("**AU**")* Letter forthcoming– Similarly, AU, Johns Hopkins, and Sibley are exploring a partnership that would provide opportunities in Medical Physics research and training for AU undergraduate and graduate physics students at Sibley.

g. *Sumitomo Heavy Industries* ("**SHI**") (Letter forthcoming) – Sibley, Johns Hopkins, and SHI are formalizing a partnership in proton therapy that includes the following:

- Purchase and sale of a state of the art proton therapy system that includes 4 treatment rooms, 3 rotational gantries and a fixed beam research room.
- Develop the Sibley Proton Therapy Center as SHI's global reference site.
- Co-Develop technology research programming at Sibley.
- Develop the Sibley Proton Therapy Center as a global training for SHI customers and clinical partners.

h. Elekta – (Letter forthcoming) Johns Hopkins and Elekta have a long standing partnership in Radiation Oncology which includes purchase transactions of equipment and software, technological research co-development, and customer reference site access. Sibley, Johns Hopkins, and Elekta are formalizing an extension of this partnership to include collaborative development of proton therapy operating system integration, proton therapy treatment planning, and proton therapy reference site access.

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE

CERTIFICATE OF NEED APPLICATION – 12-3-10

Establishment of Proton Therapy Services

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Appendix 12

No. 2554

Recorded November 9, 1896
at 9:30 A.M.

AN ACT TO INCORPORATE

[illegible] the trustees of the Lucy Webb Hayes Memorial [illegible]
[illegible] training school for deaconesses and [illegible]
[illegible] deaconesses, evangelistic and Sabbath-school workers; and a Deaconess Home; a Hospital for the care of the sick and diseased, and the training of nurses; an Orphanage for the [illegible] and care of children; and a School of Domestic Science [illegible] missionaries and deaconesses may receive systematic training in the methods of economical housekeeping, the essentials of health and nutrition, and practical scientific cookingschools, Training School for kindergarten and kitchengarden methods; and other helpful agencies as may open.

1. The property of the institution shall be held by a Board of nine trustees, who shall hold the office until successors are elected.

The following named persons are hereby incorporated as

the present members of such Board of Trustees, to-wit

Mrs. Clinton B. Fisk, New York, N.Y.; Mrs. M. H. Read, Mrs. [illegible] Mrs. John Baird Robinson, Detroit, Mich.; Bishop John F. Hurst, Judge Kossuth K. McDowell, Hon. Hiram [illegible] Price, Mrs. Clara L. Rose and W. F. Dillingham, Esq. and Evening [illegible]

District of Columbia }
} ss.
I, Henry J. Green, a Notary Public in and for the
District aforesaid, do hereby certify that Earl Granston
party to a certain amendment to the Articles of Incorporation
of the National Training School for Missionaries
bearing date the 14th day of [illegible] A. D. 1909
hereunto annexed, personally appeared before me in the
District aforesaid the said Earl Granston being personally
well known to me to be the person who executed the
said amendment to the Articles of Incorporation of the
National Training School for Missionaries and acknowledged
the same to be his act and deed.
Given under my hand and notarial seal this 18th
day of December, A. D. 1909.

Notary Public, D. C.

District of Columbia }
} ss.
I, [illegible], a Notary Public in and for the
District aforesaid, do hereby certify that [illegible]
party to a certain amendment to the Articles of Incorporation
of the National Training School for Missionaries bearing date
on the 14th day of [illegible] A. D. 1909 and here-
unto annexed, personally appeared before me, in the
aforesaid, the said [illegible]
being personally well known to me to be the persons who executed
the said amendment to the Articles of Incorporation of the National
Training School for Missionaries, and acknowledged the same to
be their act and deed.
Given under my hand and notarial seal, this 18th day
of [illegible] A. D. 1909

[illegible]
Notary Public, D. C.

We, George W. F. Swartzell, and Clara L. Ranch, being the Vice-President and Secretary, respectively, of the Lucy Webb Hayes National Training School for Deaconesses and Missionaries, a Corporation whose corporate existence will expire on the 9th day of November, A. D., 1914, do hereby certify that consent has been given to Earl Cranston, Clara L. Ranch, Al Adelaide Street, George W.F. Swartzell, William T. Gallihar, Jane Bancroft Robinson, Henrietta A. Bancroft, Dalia L. Williams and Helen Culver Jennings, who are the present Trustees of the said Lucy Webb Hayes National Training School for Deaconesses and Missionaries, to continue and extend the corporate existence of said Lucy Webb Hayes National Training School for Deaconesses and Missionaries, and that its corporate existence shall be perpetual.

WITNESS our hands and seals this Sixth day of November, A. D., 1914.

Vice-President.

Secretary.

DISTRICT OF COLUMBIA, ss:

I, [illegible], a Notary Public in and for the District of Columbia, do hereby certify that George W. F. Swartzell, Vice-President, and Clara L. Ranch, Secretary, of the Lucy Webb Hayes National Training School for Deaconesses and Missionaries, parties to a certain certificate bearing date on the [illegible] day of November, A. D. 1914, and hereto annexed, personally appeared before me in said District, the said George W. F. Swartzell and Clara L. Ranch being personally well known to me as the persons who executed the said certificate, and acknowledged the same to be their act and deed.

Given under my hand and seal this [illegible] day of November, A. D., 1914.

Notary Public, D. C.

NOTARY PUBLIC

COUNTY OF Wayne, STATE OF MICHIGAN, ss:

I, W. Frank Maxwell, a Notary Public in and for the County and State aforesaid, do hereby certify that Jane Bancroft Robinson and Henrietta A. Bancroft, parties to a certificate bearing date on the 2nd day of November, A. D., 1914, and hereto annexed, personally appeared before me in the said County and State, the said Jane Bancroft Robinson and Henrietta A. Bancroft being personally well known to me to be the persons who executed the said certificate, and acknowledged the same to be their act and deed.

Given under my hand and seal this Fourth day of November, A. D., 1914.

W. Frank Maxwell
Notary Public.

My commission expires August 1st 1916.

COUNTY OF [illegible], STATE OF OHIO, ss:

I, T. R. Owen, a Notary Public in and for the County and State aforesaid, do hereby certify that Dalia L. Williams, party to a certain certificate bearing date on the second day of November, A. D., 1914, and hereto annexed, personally appeared before me in the said County and State, the said Dalia L. Williams being personally well known to me to be the person who executed the said certificate, and acknowledged the same to be her act and deed.

Given under my hand and seal this 2nd day of November, A. D., 1914.

T. R. Owen
Notary Public.

My commission expires Sept. 28, 1917.

COUNTY OF Franklin, STATE OF OHIO, ss:

I, [illegible], a Notary Public in and for the County and State aforesaid, do hereby certify that Helen Culver Jennings, party to a certain certificate bearing date on the second day of November, A. D., 1914, and hereto annexed, personally appeared before me in the said County and State, the said [illegible] Jennings being personally well known to me to be the person who executed the said certificate and acknowledged the same to be her act and deed.

Given under my hand and seal this second day of November, A. D., 1914.

Notary Public.

My commission expires July 15, 1916.

CERTIFICATE OF AMENDMENTS TO CHARTER AND TRUSTEE CLAUSES OF CERTIFICATE OF INCORPORATION, AS AMENDED

398-10

The undersigned, John M. Dean, President, and Mrs. Joy Elmer Morgan, Secretary, of Lucy Webb Hayes National Training School for Deaconesses and Missionaries, a corporation organized under the laws of the District of Columbia (Certificate of Incorporation dated August 8, 1894, as amended), do hereby certify that, pursuant to authority granted by the Congress of the United States in the Act approved March 3, 1901, Title 29-601 et seq., of the District of Columbia Code (1951 Ed.), Mar. 3, 1901, 31 Stat. 1258, Ch. 854, Sec. 599, all of the trustees of the said Lucy Webb Hayes National Training School for Deaconesses and Missionaries have consented to two changes of the Certificate of Incorporation of said corporation, as amended, as hereinafter set forth:

A. The Object Clause as stated in Certificate of Continuance of the Corporate Existence of the Lucy Webb Hayes National Training School for Deaconesses and Missionaries, recorded November 6, 1914, in the Office of the Recorder of Deeds of the District of Columbia (Instrument #13601) reads as follows:

"Third. The particular business and object of said corporation is the preparation of Christian workers for efficient service, and to this end to conduct and maintain (1) a Bible Training School for the preparation of deaconesses, evangelistic and Sabbath school workers; (2) a Deaconess Home; (3) a hospital for the care of the sick and distressed and the training of nurses; (4) an orphanage for the training and care of children; (5) a school of domestic science, where our missionaries and deaconesses may receive systematic training in economical housekeeping, the essentials of health and nutrition and practical scientific cooking; (6) a training school for kindergarten and kindergarten methods, and such other helpful agencies as may open."

The Object Clause as changed reads as follows:

"Third. The particular business and object of said corporation is to maintain and conduct a hospital for the care and treatment of the sick and distressed and the teaching and training of nurses."

B. The Trustee Clause as stated in Certificate of Continuance of the Corporate Existence of the Lucy Webb Hayes National Training School for Deaconesses and Missionaries, recorded November 6, 1914, in the Office of the Recorder of Deeds of the District of Columbia, (Instrument #13601) reads as follows:

"Fourth. The number of trustees of said corporation for the first year of its existence under this continuance and extension of its corporate powers shall be nine, and their names and residences are as follows, to-wit:

Karl Gruenler, Washington, District of Columbia.
Clara L. Roach, Washington, District of Columbia.
A. Adelaide Street, Washington, District of Columbia.
Georgia M. F. Marshall, Washington, District of Columbia.
William T. Galliher, Washington, District of Columbia.
Jane Bancroft Robinson, Detroit, Michigan.
Mantelle A. Bancroft, Detroit, Michigan.
Lelia I. Williams, Delaware, Ohio.
Helen Culver Jandine, Cincinnati, Ohio."

The Trustee Clause as changed reads as follows:

"Fourth. The total number of trustees of the said corporation shall be such as set forth by the by laws of the corporation from time to time, but the number of trustees shall not be less than three nor more than twenty-five."

[redacted]

WITNESS our hands and seals this 2nd day of December

John M. Dean (SEAL)
John M. Dean, President

Joy Elmer Morgan (SEAL)
Mrs. Joy Elmer Morgan, Secretary

LUCY WEBB HAYES NATIONAL TRAINING SCHOOL FOR DEACONESSES AND MISSIONARIES.

STATEMENT OF ELECTION TO ACCEPT

OF

LUCY WEBB HAYES NATIONAL TRAINING SCHOOL FOR

DEACONESSES AND MISSIONARIES

To: The Recorder of Deeds, D. C.
Washington, D. C.

Pursuant to the provisions of the District of Columbia Nonprofit Corporation Act, the undersigned corporation elects to accept and avail itself of the provisions of the District of Columbia Non-profit Corporation Act.

FIRST: The name of the corporation is Lucy Webb Hayes National Training School for Deaconesses and Missionaries.

SECOND: A resolution recommending that the corporation accept the District of Columbia Non-profit Corporation Act, was adopted at a meeting of the Board of Trustees of said corporation held on April 4, 1972, at Sibley Memorial Hospital, 5255 Loughboro Road, N.W., Washington, D. C. 20016, and received the vote of a majority of the Trustees in office. There are no members of the corporation and the Trustees have full authority to take such action.

FILED
JUN 2 1 1972

THIRD: The purpose or purposes which it will hereafter pursue are as follows. The purpose and object of the corporation is to maintain and conduct a hospital for the care and treatment of the sick and distressed.

FOURTH: The corporation has no members.

FIFTH: The Trustees shall be elected annually by the Board of Trustees at its annual meeting to be held in May of each year as provided in the Bylaws.

SIXTH: Provisions for the regulation of the internal affairs of the corporation are contained in the Bylaws. Distribution of assets on dissolution or final liquidation will be as provided in the District of Columbia Non-profit Corporation Act.

SEVENTH: The registered office of the corporation in the District of Columbia is Sibley Memorial Hospital, 5255 Loughboro Road, N.W., Washington, D. C. 20016, and the name of its registered agent at such address is Bradshaw Hintmann, Esq.

EIGHTH: The names and respective addresses, including street and number, of the officers and Trustees are:

NAME	ADDRESS
Leon M. Liverell, M.D.	818 - 18th Street, N.W. Washington, D. C. 20006
Mr. L. F. McLachlan	1001 G Street, N.W. Washington, D. C. 20001
Mrs. Edwin A. Ross	Route 1, Box 276, Fair Haven Dunkirk, Maryland 20754
Dr. Albert P. Shirkey	10401 Grosvenor Place #60 Rockville, Maryland 20852
Mr. Fred W. Smith	3321 Nebraska Avenue, N.W. Washington, D. C.
Mrs. Lewis E. Smoot	"Caledon" R-2-D-477 King George, Virginia 22485
Mrs. Leonard N. Edwards	705 North Edison Street Arlington, Virginia 22203
Mr. Guy T. Stewart, II	6005 Brookside Drive Kenwood, Maryland
Dr. James W. Turner	5001 Erlola Avenue Alexandria, Virginia 22311

Date June 25, 1972

(CORPORATE SEAL)

ATTEST:

Kathryn M. Reynolds
Kathryn M. Reynolds, Its Secretary

LUCY WEBB HAYES NATIONAL TRAINING SCHOOL FOR DEACONESSES AND MISSIONARIES

By Ralph F. Gaithaller
Ralph F. Gaithaller, Its President

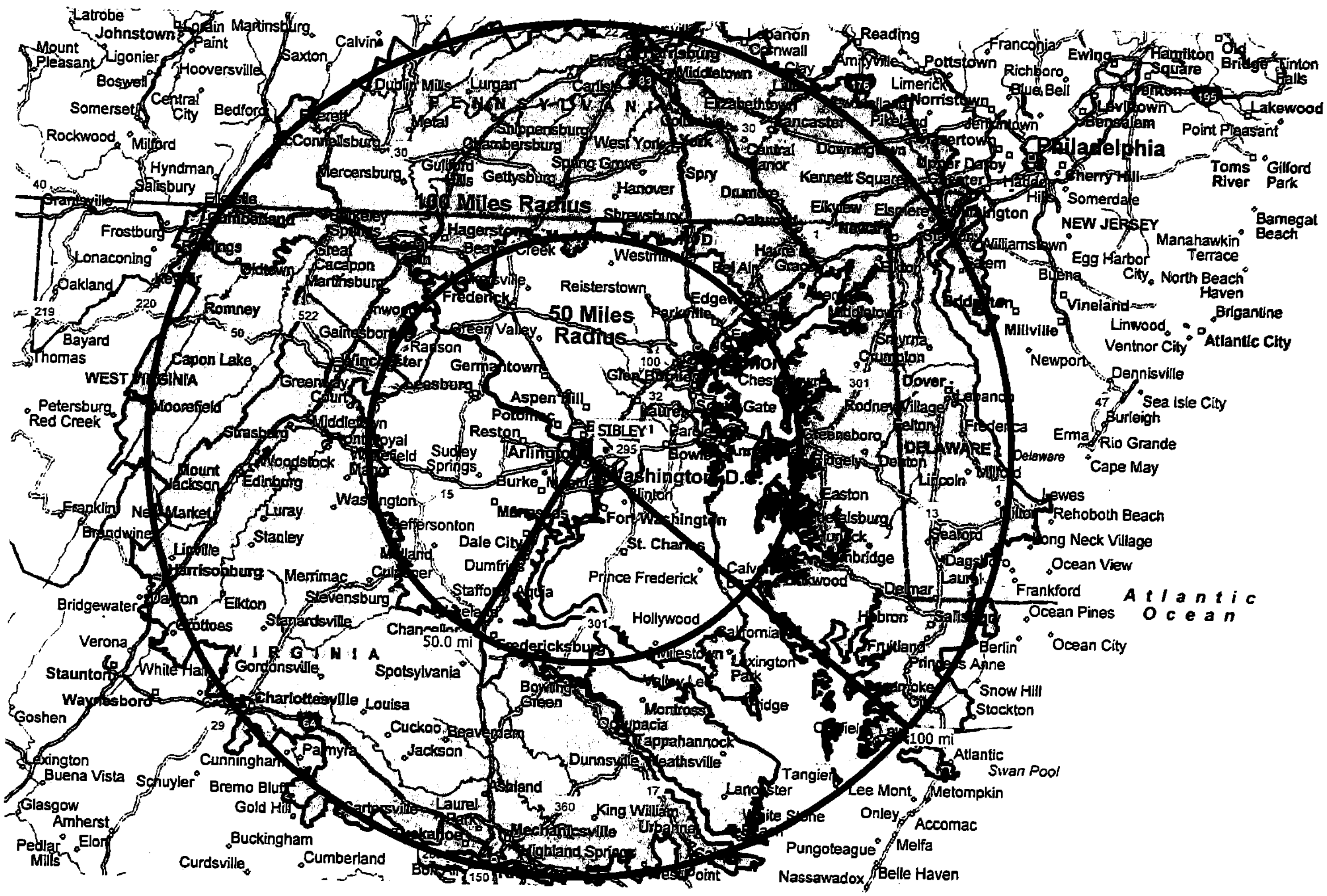
RECORDER OF DEEDS, D.C.
LEAR DIV.

1972 JUN 21 PM 1 28

Appendix 22 A

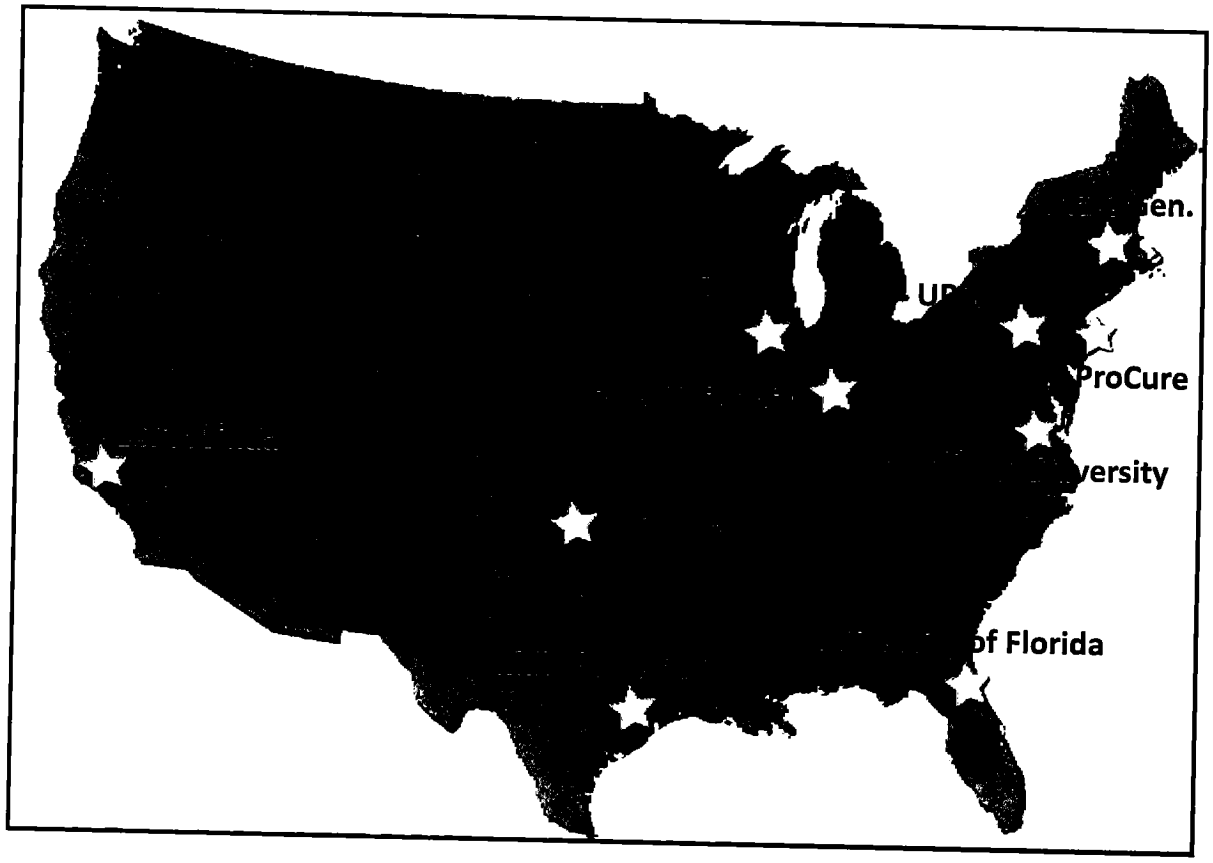
Appendix 22 – Market Area 100 Mile Radius

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE

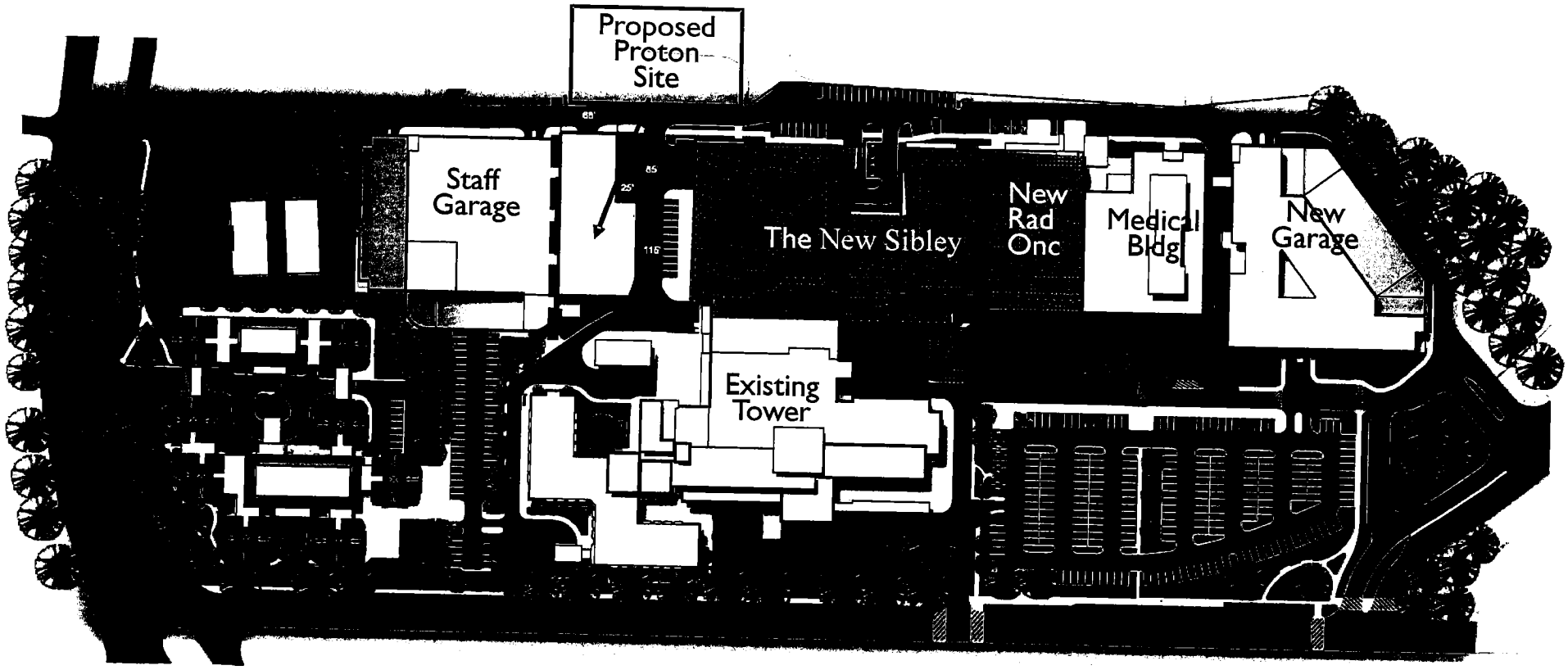


Appendix 22 B

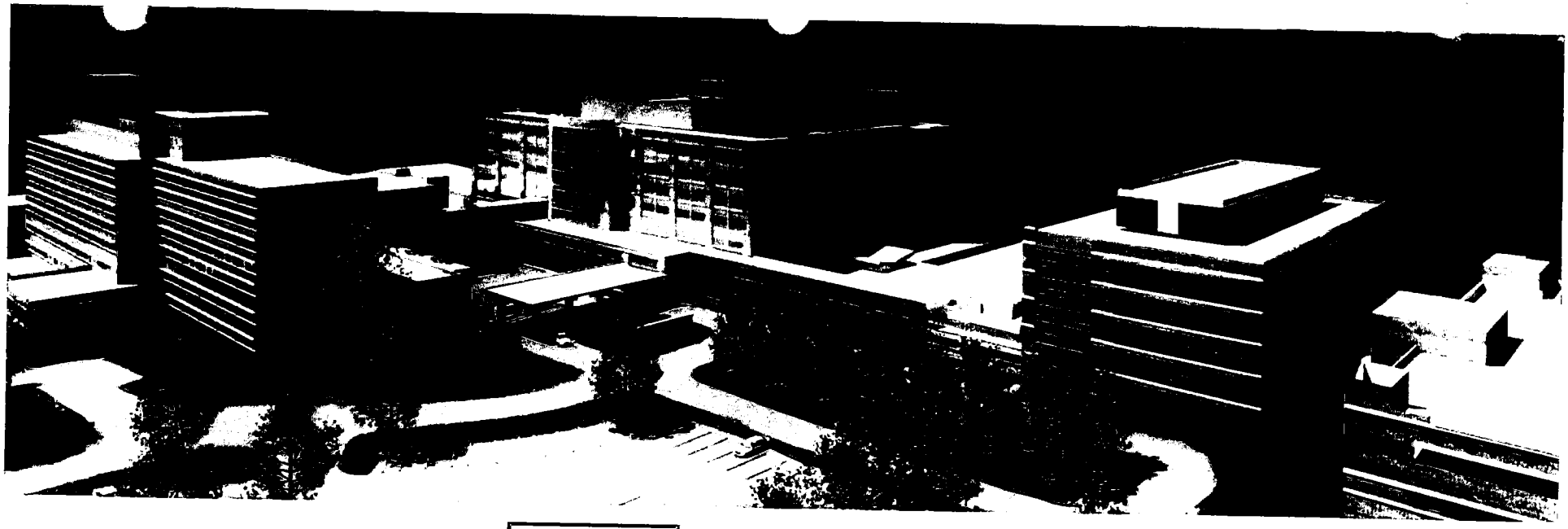
Appendix 22B. U.S. Proton Therapy Centers

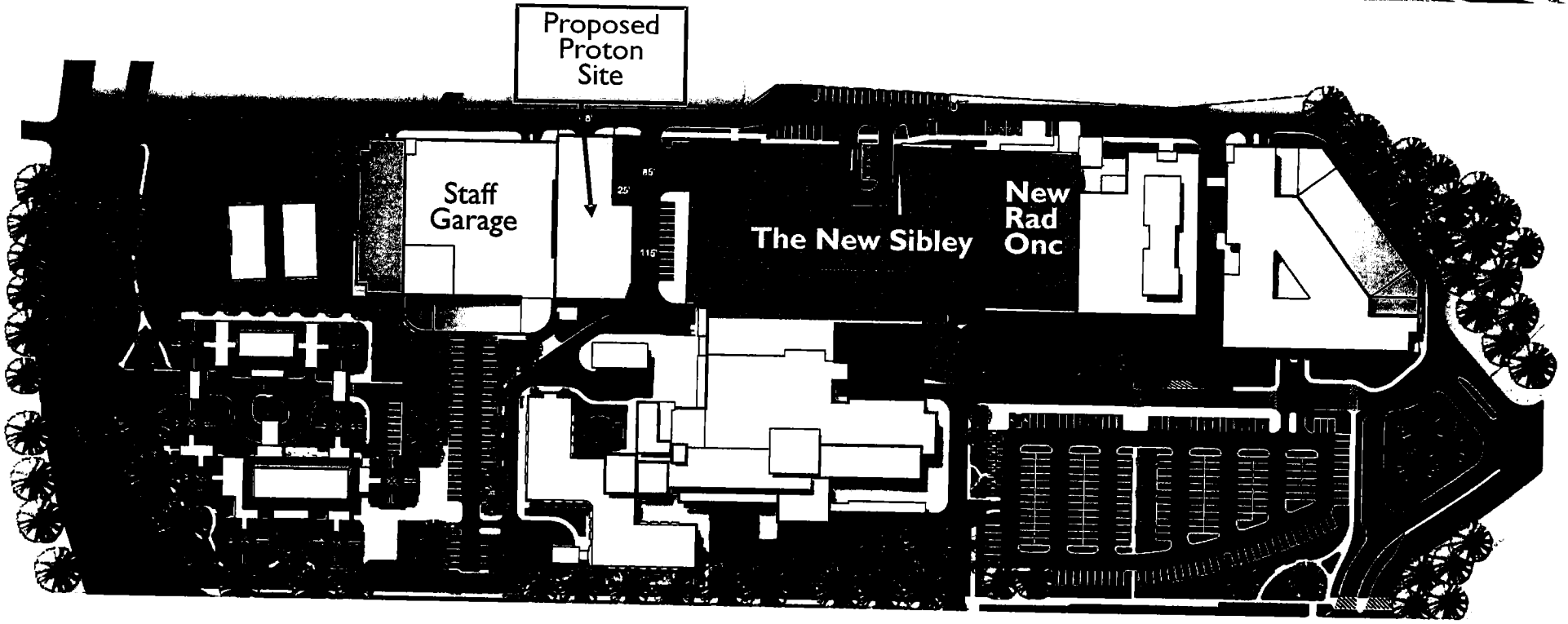


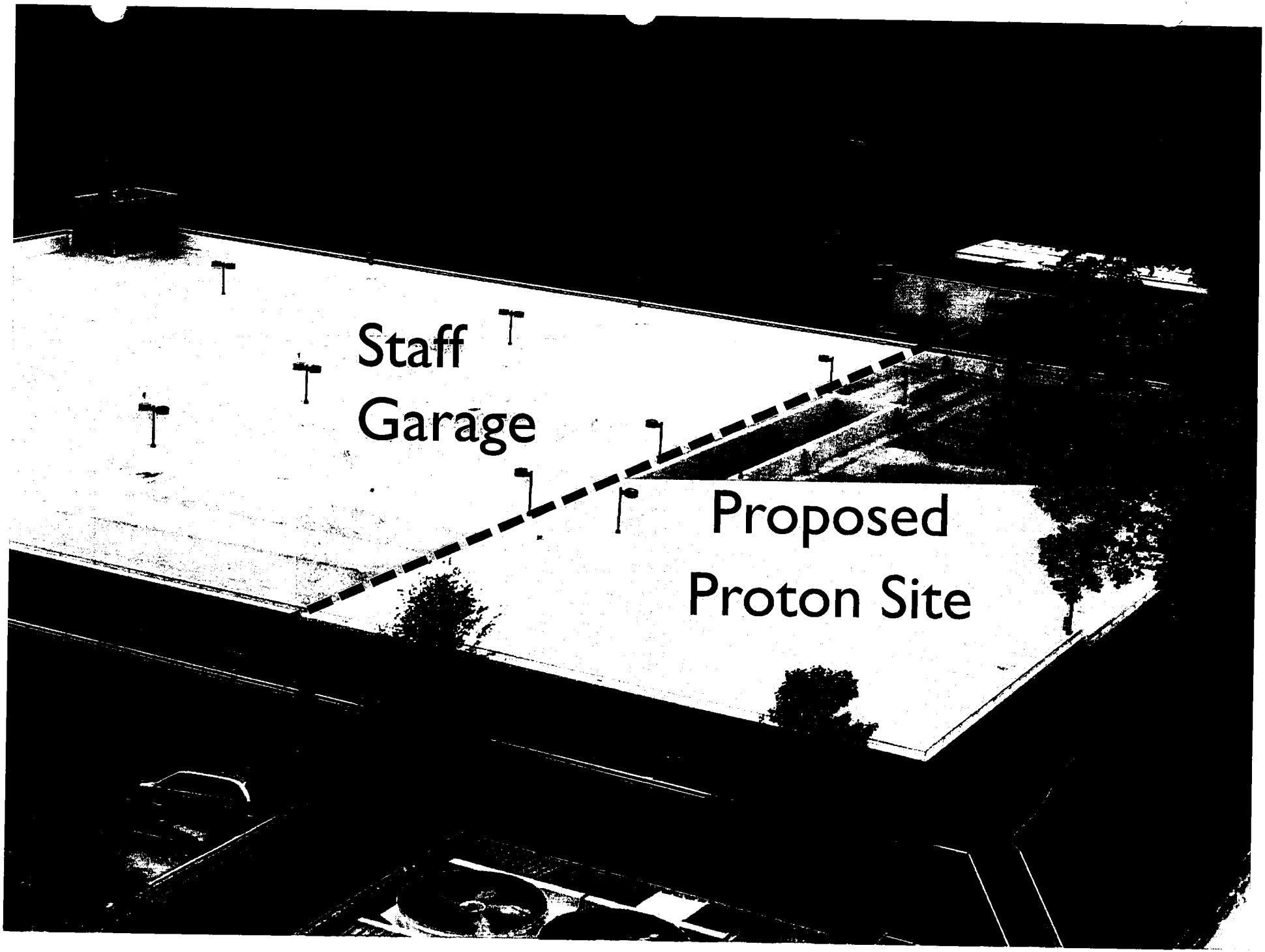
Appendix 23 A – C



Campus Site Plan




Proposed
Proton
Site
Staff
Garage
The New Sibley
New
Rad
Onc

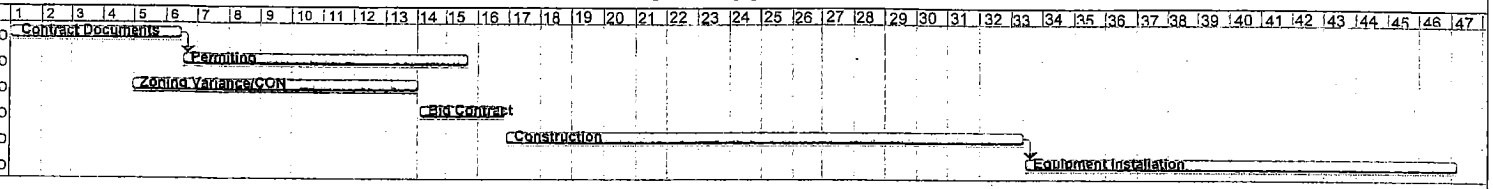

Staff
Garage
Proposed
Proton Site

Appendix 24

DRAFT

Proton Timeline - From Project Approval

ID	Task Name	Duration
1	Contract Documents	6 mo
2	Permiting	10 mo
3	Zoning Variance/CON	10 mo
4	Bid Contract	3 mo
5	Construction	18 mo
6	Equipment Installation	15 mo



Project: 11.09.01 Proton Timeline
Date: Thu 10/6/11

Task | Progress | Summary | External Tasks | Deadline
Split | Milestone | Project Summary | External Milestone

Appendix 48 A

The New York Times
Opinionator

JANUARY 2, 2012, 10:18 PM

It Costs More, but Is It Worth More?

By EZEKIEL J. EMANUEL and STEVEN D. PEARSON

If you want to know what is wrong with American health care today, exhibit A might be the two new proton beam treatment facilities the Mayo Clinic has begun building, one in Minnesota, the other in Arizona, at a cost of more than $180 million dollars each. They are part of a medical arms race for proton beam machines, which could cost taxpayers billions of dollars for a treatment that, in many cases, appears to be no better than cheaper alternatives.

Proton beam therapy is a kind of radiation used to treat cancers. The particles are made of atomic nuclei rather than the usual X-rays, and theoretically can be focused more precisely on cancerous tissue, minimizing the danger to healthy tissue surrounding it. But the machines are tremendously expensive, requiring a particle accelerator encased in a football-field-size building with concrete walls. As a result, Medicare will pay around $50,000 for proton beam therapy for a patient with prostate cancer, roughly twice as much as it would if the patient received another type of radiation.

The higher price would be worth it if proton beam therapy cured more people or significantly reduced side effects. But there is no evidence showing that this is true, except for a handful of rare pediatric cancers, like brain and spinal cord cancer. For children, the treatment does a better job of limiting damage to normal brain cells and reducing the risk of cognitive impairment and hearing loss. But - fortunately - fewer than 3,500 American children get these cancers each year. It is impossible to keep all nine existing proton beam centers in full use, much less the approximately 20 others in planning or construction, with so few patients.

To generate sufficient revenue, proton beam facilities need to treat patients with other types of cancer. Consequently, they have been promoted for patients with lung, esophageal, breast, head and neck cancers. But the biggest target by far has been prostate cancer, diagnosed in nearly a quarter of a million men each year.

There is no convincing evidence that proton beam therapy is as good as - much less better than - cheaper types of radiation for any one of these cancers. There has not been a single randomized trial, only small, short-term studies. Such trials cannot evaluate the therapy's long-term outcomes, nor resolve the concerns that some experts have raised regarding a potentially increased risk of hip fractures, bowel problems or other delayed effects associated with the therapy's treatment for prostate cancer.

So why is the venerable Mayo Clinic building two proton beam facilities? Because it's competing against Massachusetts General Hospital, M. D. Anderson in Texas, the University of Pennsylvania, Loma Linda in California - all of which have one. With Medicare reimbursement so generous, and patients and doctors eager for the latest technology, building new machines is sane, profitable business for hospitals like Mayo.

But it is crazy medicine and unsustainable public policy.

One solution is for Medicare to simply refuse to pay for proton beam treatment except for diseases where there is valid evidence that it is clinically superior, as many private insurers do. This would certainly help keep costs down, and it would also encourage manufacturers and researchers to actually conduct studies comparing proton beam therapy to other treatments.

However, it is often difficult to begin clinical trials without some reimbursement for the treatment that is being studied. So a second option is "coverage with evidence development." In this approach, Medicare would pay for proton beam treatment for patients with prostate and other cancers, but only if the patients were enrolled in a randomized trial that would compare the outcomes of their treatment to those from surgery, other kinds of radiation or active surveillance. Medicare has used this approach sparingly, but it should be applied to more cases like this one.

The most promising option is a new approach called dynamic pricing. Medicare would pay more for proton beam therapy, but only for diseases that are proven to be treated more effectively by the therapy than by other forms of radiation. For cancers like prostate, it would pay only what it pays for the cheaper alternatives. But if studies were done showing that proton beam therapy was better than other treatments, the payment would go up. If no studies were done, or the new evidence demonstrated no advantages, then coverage would continue, but at the lower reimbursement.

Of course hospitals could continue charging patients more for proton beam therapy, and patients who wanted the treatment could pay the difference themselves. But this should not be seen as unfair to those who can't afford it, because there are alternatives that are just as effective.

Everyone wants the best available care, especially for life-threatening diseases like cancer. But that doesn't mean Americans should pay exorbitant costs for treatments that can't be shown to be better than other, cheaper, options. If the United States is ever going to control our health care costs, we have to demand better evidence of effectiveness, and stop handing out taxpayer dollars with no questions asked.

Ezekiel J. Emanuel, an oncologist and former White House adviser, is a vice provost and professor at the University of Pennsylvania. Steven D. Pearson, a general internist, is the president of the Institute for Clinical and Economic Review at the Massachusetts General Hospital's Institute for Technology Assessment.

A version of this article ran in print on January 3, 2012.

Appendix 51 A

Appendix 51 C

Appendix 51 D-F

Acta Oncologica, 2005; 44: 836–849

Taylor & Francis
Taylor & Francis Group

ORIGINAL ARTICLE

Number of patients potentially eligible for proton therapy

BENGT GLIMELIUS[1], ANDERS ASK[2], GÖRAN BJELKENGREN[3], THOMAS BJÖRK-ERIKSSON[4], ERIK BLOMQUIST[1], BENGT JOHANSSON[5], MIKAEL KARLSSON[6] & BJÖRN ZACKRISSON[7]

[1]*Department of Oncology, Radiology and Clinical Immunology, Akademiska sjukhuset, Uppsala and Department of Oncology and Pathology, Karolinska Institutet, Stockholm,* [2]*Department of Oncology, University Hospital, Lund,* [3]*Department of Oncology, University Hospital, Malmö,* [4]*Department of Oncology, University Hospital, Gothenburg,* [5]*Department of Oncology, University Hospital, Örebro,* [6]*Department of Radiation Physics, University Hospital, Umeå and* [7]*Department of Oncology, University Hospital, Umeå, Sweden*

Abstract

A group of Swedish radiation oncologists and hospital physicists have estimated the number of patients in Sweden suitable for proton beam therapy in a facility where one of the principal aims is to facilitate randomized and other studies in which the advantage of protons can be shown and the magnitude of the differences compared with optimally administered conventional radiation treatment, also including intensity-modulated radiation therapy (IMRT) and brachytherapy, can be shown. The estimations have been based on current statistics of tumour incidence in Sweden, number of patients potentially eligible for radiation treatment, scientific support from clinical trials and model dose planning studies and knowledge of the dose-response relations of different tumours together with information on normal tissue complication rates. In Sweden, it is assessed that between 2200 and 2500 patients annually are eligible for proton beam therapy, and that for these patients the potential therapeutic benefit is so great as to justify the additional expense of proton therapy. This constitutes between 14–15% of all irradiated patients annually.

Radiation therapy plays an important role in curative and palliative tumour treatments and projections show that it will in the future play an even increasingly important role [1–3]. It has continuously improved ever since radiation beams were detected more than a century ago, and this improvement is likely to continue. Radiation therapy research and development, however, also faces many challenges, some of them financial [2]. In spite of large investment costs, radiation therapy remains a comparatively low-cost curative treatment modality [4]. In radiation therapy, investment costs of equipment have to be borne by the hospitals/providers of health care, in contrast for example to medical oncology, where all investment costs are borne by the drug companies, in the hope of new drugs being paid for by hospitals for each individual patient as a result.

Protons have physical properties that will confer dose distribution advantages compared to the conventional rays, photons and electrons. These advantages will result in lower doses to surrounding, non-tumour-containing tissues with reduced acute and late toxicities, and/or higher doses to the tumour with increased probabilities of tumour control. The lower doses to normal tissues may also result in improved tolerance of chemotherapy or other drugs which are being increasingly given with radiation [5]. The distribution advantages may convince fellow radiation oncologists, and thus the experts, but a proven effect on patient-related outcomes must be shown to convince the non-experts [6–8]. Still, dose distribution advantages have generally been sufficient in the past to motivate new investments in high technology treatments. This is no longer the case, partly because of financial constraints, but mainly due to recognition of the importance of evidence-based medicine [6,9,10]. The dose distribution advantages using protons, seen in a number of comparative dose planning studies, must be explored in properly controlled clinical trials to prove

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a sufficiently increased clinical gain in increased tumour cure or improved tolerability.

In spite of almost 43 000 patients being treated with protons worldwide [11], there is an almost complete lack of controlled clinical trials. This is not to say that conclusions cannot be drawn regarding the value of proton therapy from this extensive clinical experience. The many thousand patients with uveal melanoma who have been treated have given 95% local tumour control after 15 years and a retained eye in 84% of cases [4,12]. These results are unlikely to be achieved with any other technique, at least not in cases of larger tumours and tumours located close to the optic nerve. Similarly, the results from the thousands of patients with skull base tumours who have received proton or ion beam treatment have shown clear advantages in the form of better tumour control with unchanged risk of complications compared with those attainable with conventional types of radiation [6,13,14]. Similar experience has been achieved in several studies in the treatment of solid tumours in children. Some improvements in oncology are so evident that randomized clinical trials are impossible to run, being actually unethical. However, patient selection is also important for outcome, and apparently marked improvements may frequently turn out to be absent or at best marginal when the properly controlled clinical trials are performed. This also applies to radiation therapy.

In order to provide better knowledge about the clinical value of proton therapy, prior to a decision to invest in a facility capable of running large clinical trials, i.e. to create better scientific evidence, a national group of experts evaluated the entire literature to estimate the potential number of patients for whom there are potentially sufficient clinical gains to motivate the higher investment costs. A report was originally written in Swedish (available at http://qp1.lul.se/QuickPlace/sptc/Main.nsf) and has now been partly translated and updated to June 2005.

Methods

Estimation of potential number of patients

The number of patients for a new therapy, in this case proton therapy, depends on the number of patients with diseases where the treatment in clinical trials has proved to be better than previous therapies. Since this investigation was made to provide support for an investment in a research facility capable of revealing improved treatment results in clinical trials, the estimations cannot be based upon strong evidence from clinical trials.

A systematic approach to the literature was used [10,15]. A computerized search of the literature was performed in Medline and in the Cochrane Library. These searches had to include mainly clinical trials providing limited scientific information (phase I and II trials) as well as model studies comparing dose distributions achieved with conventional techniques and protons. These model studies have, in one or a limited number of patients, compared the dose distributions achieved with different radiation techniques. They have generally evaluated the physical dose distributions but sometimes also used biological models, estimating the probability of tumour control (TCP) and the probability of normal tissue complications (NTCP).

The number of patients of different ages with a certain type of cancer is obtained from population statistics, and these are well developed in the Nordic countries (e.g. Cancer Incidence in Sweden). Evidence-based indications for radiotherapy in general [16] and in specific tumour types have been estimated in several studies [17–35], and this information was used by the group to get an estimate of the number of patients with the different cancer types in different stages treated with radiation therapy. The differences between these sources of radiotherapy utilization and evidence-base have been discussed [36]. The most relevant information, for this investigation, about the number of patients irradiated was obtained from the 12-week survey performed by the Swedish Council on Technology Assessment in Health Care (SBU) group [37].

Evaluation of the literature and evidence-base for the estimations

The literature for the various diagnoses of interest for radiation therapy was first evaluated by one member of the team. A preliminary draft with conclusions was prepared. This was then scrutinized by the rest of the group and a joint manuscript prepared. The manuscript was sent to all Swedish radiation therapy experts in the different diagnoses, and modifications were made. Finally, the writing was evaluated by invited specialists from the other Nordic countries and a joint decision was taken.

The scientific evidence for proton therapy is not very high according to generally held agreements [10]. In Table I, describing the potential number of patients eligible for proton therapy, the tumour types are ranked according to the clinical experience reported so far, albeit from phase I and II trials only, differences seen in the dose planning model studies, and knowledge about dose-response relationships. For those listed in the top there is very high or high support that protons will be used in

Table I. Estimate of the number of cases from Sweden eligible for proton beam therapy.

Tumour type[1)]	No. new cases in Sweden per annum	No. radiotherapy treatments in Sweden per annum[2)]	Suitable no. patients proton therapy
Intraocular melanoma	75	?	15
Skull-base chordoma/chondrosarcoma	30	?	20–25
Meningeoma	300	40	30–40
AVM	70	?	20–25
Medulloblastoma	30	30	20
Reirradiations		?	150–400
Paediatric cancer (not incl. medulloblastoma)	300	90–100	60–80
Pituitary adenoma	?	?	10–15
ENT cancer-nasopharynx/sinus	80	80	60
Sarcoma	375	175	40
ENT cancer-others	920	570	240
Oesophageal cancer	400	150	80
Rectal cancer	1800	830	150
Breast cancer	6300	3370	300
Thymoma	30	?	20
Lung cancer	2850	485	350
Gynaecological cancer	2700	650	50
Malignant gliomas	375	200	50–75
Cancer of the liver	400	70?	65+
Mesothelioma	100	?	20
Prostate cancer	7800	1420	300
Malignant lymphomas	2000	460	20
Urinary bladder cancer	2300	180	?
Pancreatic cancer	800	50	50?
Gastric cancer	1100	70?	?
Palliations			90
	31 050	7650[3)]	2220–2475+

[1)] The tumour types are listed according to the support in favour of these treatments being given with protons in routine medical care (at the top) or that there are very good (middle) and good prospects (bottom), respectively, of clinical studies showing clinically relevant, "cost-effective" benefits.

[2)] The number of patients, according to the SBU survey, receiving external radiotherapy with a curative purpose in the diagnoses evaluated.

[3)] 9100 treatments were given to 7650 patients.

routine health care, whereas for those listed in the middle and lower part of the table there are very good or good possibilities that randomized clinical trials could show clinically relevant and "cost-effective" gains.

Results

The number of patients potentially eligible for proton therapy each year in Sweden amounts to between 2200 and 2500 (Table I). This figure constitutes about 14–15% of the number of patients (n = 16 000 in the year 2001 according to the SBU-survey [37]), who each year receive radiation therapy in Sweden. A brief summary is given below for each of the diagnoses. A more complete description of the various diagnoses will be found in separate articles. The diagnosis articles also contain a description of the results seen in the model dose planning studies which, without exception, reveal potential advantages using proton beams in one or several aspects compared to the conventional beams. The identified model studies are listed in Table II, which also includes a brief description of the main results.

Intraocular melanoma

Proton irradiation is an established therapy for intraocular melanoma, mainly for large melanomas and melanomas located on or adjacent to the optic nerve and iris. Some 15 patients annually may be eligible.

Base of skull chordoma and chondrosarcoma

Better dose distribution means greater tumour control and less risk of long-term side-effects in the majority of these patients, i.e. 20–25 patients per annum. These tumours are routinely treated with protons wherever possible. Encouraging experiences have also been reported using ion therapy.

Meningeoma

Better dose distribution with less risk of long-term side-effects can imply clear advantages to 30 or 40

Table II. Comparative dose planning studies.

Reference	Year	Tumour type	Number of patients planned	Photons		Protons		Comments
				3D-CRT	IMXT	Regular	Scanned	
Suit et al. [59]	1988	Cervical cancer	1	X		X		Better dose distributions with improved local control, less toxicity
Brown et al. [60]	1989	Nasopharynx	2	X		X		Better dose distributions with improved local control, less toxicity
Urie+Gotein [61]	1989	Chordoma/ chondrosarcoma	12	X		X	X	Variably (intensity) modulated protons reduce dose to normal tissues (integral dose by 3–12%-units) compared to fixed (SOBP) protons, however, the largest difference was between protons and photons (2 patients)
Austin-Seymour et al. [62]	1990	Skull base	1	X		X		Less dose to OARs, e.g. the optic nerve
Austin-Seymour et al. [62]	1990	Prostate	1	X		X		Less dose to OARs
Tatsuzaki et al. [63]	1991	Rectum	1	X		X		Reduced dose to small bowel using protons
Archambeau et al. [64]	1992	Thalamic pediatric astrocytoma	1	X		X		Improved dose distribution, lower normal brain dose, higher tumour dose possible
Gademann & Wannenmacher [65]	1992	Pediatric retroperitoneal tumour	1	X		X		Better dose localization, less second cancers
Levin [66]	1992	Para-aortic nodes, cervical cancer	1	X		X		Higher doses could be reached using protons, improved tumour control by 10–20%
Miralbell et al. [67]	1992	Maxillary sinus	1	X		X		Less dose to OARs using a proton boost
Slater et al. [68]	1992	Tonsil	2	X		X		Superior dose distributions, higher tumour doses, less doses to OARs (chiefly mandible parotic glands)
Smit [69]	1992	Cervical cancer	1	X		X		Higher doses (by 20%) could be reached using protons, 40% increase in tumour control
Tatsuzaki et al. [70]	1992	Glioblastoma	1	X		X		Less dose to non-target brain using protons
Wambersie et al. [71]	1992	Pediatric brain tumours	3	X		X		Less dose to non-target brain using protons
Miralbell & Urie [72]	1993	Large AVM	1	X		X		Less dose to non-target brain, brain stem and optic chiasm using protons
Lee et al. [73]	1994	Prostate	12	X		X		Distinctly reduced rectal NTCP using protons in one-third of the cases, minimal gain in the remaining
Isacsson et al. [74]	1996	Rectum	6	X		X		At 5% NTCP in any organ, TCP is increased by 14%-units with protons
Isacsson et al. [75]	1997	Ewing/paraspinal	1	X		X		At 1% NTCP in spinal cord, TCP in increased by 5%-units
Miralbell et al. [76]	1997	Medulloblastoma-supratentorial target	1	X	X		X	Better sparing of normal tissues with protons and IMXT compared to conventional with less IQ-reduction
Miralbell et al. [77]	1997	Medulloblastoma-spina techa target	1	X	X		X	Decreased dose to all OARs using protons
Sandison et al. [78]	1997	Chest wall	1	X		X		Less lung dose using protons
Isacsson et al. [79]	1998	Oesophagus	5	X		X		At 5% NTCP in any organ TCP is increased by 20%-units (from 2 to 25%) with protons
Verhey et al. [80]	1998	CNS	5	X		X		Less dose to normal brain
Fuss et al. [81]	1999	Optic nerve, gliomas	7	X		X		CI 2.9 photons, 2.3 protons, larger differences in larger tumours

Table II (*Continued*)

Reference	Year	Tumour type	Number of patients planned	Photons		Protons		Comments
				3D-CRT	IMXT	Regular	Scanned	
Glimelius et al. [47]	1999	Sacral chordoma	1	X		X		Lower doses to rectum and urinary bladder using one proton beam compared to 3D-CRT photons
Lee et al. [82]	1999	Lung	13	X		X		More patients could be treated to higher tumour doses using protons compared to any photon technique
Lomax [83]	1999	Nasopharynx	1			X	X	Intensity modulation show advantages when few beams are used
Lomax et al. [84]	1999	Various	9	X	X		X	Reduced medium to low dose for protons compared to IMXT
Fuss et al. [85]	2000	Pediatric optic nerve glioma	7	X		X		Reduced NTCPs, likely clinically significant for cognitive impairment
Lin et al. [86]	2000	CNS, pediatric fossa	9	X		X		Protons result in increased normal tissue sparing, e.g. the cochlea (25% of dose compared to 75% of prescribed dose)
Miralbell et al. [87]	2000	Orbital and paraorbital	4		X		X	Similar PTV coverage, lower integral doses to OARs (x1.5–1.9), predicted NTCPs (severe late tox) similarly low
Oelfke+Bortfeld [88]	2000	–			X	X	X	IMPT advantages to SOBP protons and IMXT in a theoretical study, integral dose 30% lower using IMPT vs SOBP, a factor 2–3 vs IMXT
Paulino et al. [89]	2000	Medulloblastoma	5	X		X		Lower doses to all OARs
Smith et al. [90]	2000	Multiple sites	10+	X	X	X	X	Improved clinical outcomes at all sites, reduced NTCPs/higher TCPs
Zurlo et al. [91]	2000	Pancreas/biliary	4	X	X		X	Protons allowed delivery of planned dose in all patients, not or barely possible with photons
Baumert et al. [92]	2001	CNS	7	X			X	For complex PTV shapes and when PTV close to critical organs, protons yield better dose distributions than photons for SRT
Cella et al. [93]	2001	Prostate	1	X	X	X	X	Both IMXT and IMPT gave better dose distributions than non-IM plans and less NTCP in rectum, all proton plans improved PTV homogeneity and reduced medium-low dose in normal tissues compared to the photon plans
Cozzi et al. [94]	2001	Head and neck	5	X	X		X	Protons give improved dose homogeneity, higher EUD, better preserved organ function and quality of life
Johansson et al. [95]	2002	Breast	11	X	X	X		Lowest NTCP values for protons for the heart (0.5 vs 2.1%) and lung (0.6 vs 124.7%) compared with the best other plan
Miralbell et al. [96]	2002	Pedicatric rhabdomyosarcoma	1	X	X	X	X	Reduced risk of sec. malignancy by ≥ 2
Miralbell et al. [96]	2002	Medulloblastoma	1	X	X	X		Reduced risk of sec. malignancy by a factor of 8–15
Bolsi et al. [97]	2003	Small intracranial, different tumours	12	X	X	X	X	Improved CI, reduced OAR dose at all sites, less sec. cancer induction
Lomax et al. [98]	2003	Breast	1	X	X	X		Protons spare lungs and heart better than IMXT/standard treatment
Lomax et al. [99]	2003	Paranasal sinus	1		X		X	Critical structures could be spared best by protons at all dose levels
Suit et al. [14]	2003	Rectum	1		X	X		Improved dose distribution, less toxicity
Johansson et al. [100]	2004	Hypopharynx	5	X	X	X	X	Protons give lower non-target doses compared to 3D-CRT/IMXT. NTCP parotid glands 40–43% protons, 51–65% IMXT, 93+% 3D-CRT

Table II (*Continued*)

Reference	Year	Tumour type	Number of patients planned	Photons			Protons		Comments
				3D-CRT	IMXT	Regular	Scanned	
Mock et al. [101]	2004	Paranasal sinus	5	X	X	X		Similar CI but reduced doses to OAR (by 60%) and integral doses using protons
St Clair et al. [102]	2004	Medulloblastoma	1	X	X	X		Substantial normal tissue sparing, e.g. to the cochleas and the heart
Weber et al. [103]	2004	Paraspinal sarc	5		X		X	Similar conformity, reduced integral dose to OARs, dose escalation to 93 CGE possible with protons
Yoch+Tarbell [104]	2004	Pediatric, CNS	2	X	X	X		Better dose homogeneity and conformity
Krengli et al. [105]	2005	Retinoblastoma	3	X		X		Protons can achieve significant lens sparing and reduced risk of second malignancies
Mu et al. [106]	2005	Medulloblastoma	5	X	X		X	Risk second cancer conv RT 18%, IMXT 28%, IMPT 4%

Abbreviations: CI = conformity index; IMXT = intensity-modulated photon therapy; IMPT = intensity-modulated proton therapy; TCP = tumour control probability; NTCP = normal tissue complication probability; SRT = stereotactic radiotherapy; OAR = organ at risk; EUD = equivalent uniform dose; SOBP = spread-out Bragg peak.

patients annually. There is good experience of administering proton therapy for one week instead of the conventional five or so.

Arteriovenous malformations (AVMs)

For AVMs exceeding 10 cm^3 in size, protons afford a better possibility than any other technique of achieving complete obliteration. Some 20 or 25 patients annually are potentially eligible.

Medulloblastoma

Patients with medulloblastoma and related tumours, occurring mainly in children, derive benefit from the improved dose distribution of protons. There is a degree of uncertainty regarding the number of cases, but it is estimated that at least 20 patients per annum can be treated.

Reirradiation

It is estimated that about 150 patients in need of reirradiation are potentially eligible for proton therapy every year, since the volume of tissue irradiated has to be limited according to the radiation therapy administered previously. In this way the chances of local tumour control and, accordingly, cure should be increased, at the same time as adverse effects should be reduced.

Paediatric cancer (other than medulloblastoma)

Between about 60 and 80 of the 100 or so children irradiated annually for a malignancy of one kind or another (excluding medulloblastoma) are suitable for proton therapy, since the risk of serious late complications can be reduced. It is theoretically possible to raise the radiation dose for radioresistant paediatric tumours and achieve better tumour control.

Pituitary adenoma

Some 10 or 15 patients with endocrinologically active adenoma which, despite medical treatment, cannot be adequately controlled are suitable for proton therapy as routine treatment.

Cancer of the ear, nose and throat region

Some 30% or about 300 of the almost 1100 new cases of these cancers diagnosed annually in Sweden are judged to benefit from a higher radiation dose for better tumour control, at the same time as the radiation dose to critical organs can be reduced, and with it the risk of long-term side-effects, e.g.

xerostomia. Tumours growing in and near the base of the skull, e.g. nasopharyngeal cancer and paranasal sinus tumours are likely treated as a part of routine medical care, while other treatments should be given in studies where it is possible to show either greater tumour control or fewer long-term side-effects.

Sarcoma

Proton therapy for sarcoma is of great importance for tumours close to critical risk organs, e.g. tumours in the base of the skull, the orbit and the spine. Proton therapy may possibly also have advantages in advanced unresectable retroperitoneal sarcomas. The number of patients, however, is small, totalling about 40 per annum (skull base chordoma and chondrosarcoma are not included in this figure).

Oesophageal cancer

Increased radiation dose to the tumour simultaneously with the possibility of reducing the dose to adjacent sensitive structures may mean improved treatment outcomes. About 80 patients are judged eligible for inclusion in a clinical study.

Rectal cancer

It is estimated that primarily 150 patients annually with primarily unresectable rectal cancer growing onto adjacent organs may be eligible for proton therapy. If so, treatment of this kind can give greater tumour control, at the same time as the acute and long-term side-effects can be limited.

Breast cancer

It is estimated that primarily 300 patients in Sweden who are at risk of heart and lung adverse effects can be eligible for proton therapy, given the possibility. The risks of heart/lung complications and the risk of secondary malignancy should then be reduced to very low levels. The treatment should take place in a prospective study where the risk of complications with advanced 3D-CRT/IMRT can be quantified according to the dose to these organs, and in which the outcome for proton-treated patients can be observed after prolonged follow-up.

Thymoma

It is estimated that more than half the thymoma cases diagnosed in Sweden, corresponding to 20 patients, would be eligible for proton therapy within the framework of clinical studies, if treatment of this kind were available in Sweden. Potential benefits of such treatment mainly comprise reduction of acute and long-term side-effects prominently occurring in connection with the large treatment volumes of the thoracic cavity and the radiation doses used today.

Lung cancer

An estimated 350 lung cancer patients annually are eligible for proton therapy. Most of them should be included in clinical studies. Proton therapy is judged in the majority of cases to present advantages in the form of less radiation to surrounding risk organs and the possibility of dose escalation, which can mean better long-term survival.

Gynaecological cancer

Brachytherapy plays an important role in the treatment of gynaecological cancer, for the achievement of local tumour control. There is very great uncertainty concerning the value of protons, but their use is unlikely to become widespread. In cases where, for some reason, brachytherapy is not technically feasible, protons can offer a possibility of increased local control compared with conventional external radiotherapy. At the present state of knowledge, the number is of the order of 50.

Malignant glioma

There is great uncertainty regarding the value of protons in cases of malignant glioma. Better dose distribution with a lower dose administered to an adjacent and apparently normal brain, and a high dose to a visible tumour with a margin, can mean better quality of life and possibly prolonged survival for 20 or 25% of the patients. This applies above all to younger patients with astrocytoma grade III, among whom survival can sometimes be long. Between 50 and 75 patients annually may become eligible for treatment, all of them in prospective studies. The number of patients potentially includible in a randomized study comparing protons with photons is 100–150.

Liver cancer

It is estimated that primarily 65 Swedish patients annually with primary cancer of the liver can be eligible for proton therapy, given the possibility. The chances of local tumour control and, accordingly, survival prospects, might then increase. The treatments should take place in randomized studies. There is a future potential here for a much greater number of patients, above all patients with metastases from colorectal cancer, than stated above.

Mesothelioma

At present this is a grim disease with a grim prognosis and little possibility of treatment. Only about 20 patients annually can be judged eligible for proton therapy, which should make possible a higher dose without any additional risk of complications.

Prostate cancer

It is estimated that in the first instance some 300 patients in Sweden annually are eligible for proton therapy, given the possibility. This therapy can give increased probability of tumour control without increased side-effects compared with the present therapy. About 200 of the 300 patients are primarily at stage T3N0, and the remainders have undergone non-radical surgery. The larger the tumour is locally, the greater the role which protons are capable of playing, but in that case the risk of distant metastasis is also greater, and the impact on total survival is impossible to assess. Local tumour control, however, is a precondition of long-term survival.

Malignant lymphoma

An estimated 20 or so patients annually with Hodgkin's lymphoma (HL) can be treated with reduced risks of long-term complications. If, however, a proton facility is available, more patients can be considered, i.e. including also certain patients with non-Hodgkin lymphoma. Knowledge based on randomized studies will probably be unobtainable, since conclusive results concerning reduced long-term complications can only be expected after 10 or 20 years follow-up.

Cancer of the urinary bladder

It is estimated that between 100 and 150 bladder cancer patients in Sweden per annum undergo radiotherapy with a curative purpose. It is impossible to judge the fraction of these patients who may benefit from proton therapy. Ion therapy is hardly to be considered, since it is uncertain whether the bladder wall can tolerate the higher biological doses which are then administered against the primary tumour located in the bladder wall.

Pancreatic cancer

Potentially up to 240 patients annually may be eligible for a clinical study evaluating proton therapy. This figure is, however, probably too high in relation to the present state of knowledge and therapy tradition, but pancreatic cancer is a diagnosis for which a clinical facility in Sweden can mean the possibility of carrying out randomized studies to judge whether long-term survival can increase for one of the diagnoses having the worst prognosis of all cancers.

Gastric cancer

There is great uncertainty regarding the value of irradiation for gastric cancer, although a major American study has shown such a survival gain that post-operative radiation therapy in large volumes is routinely administered by many centres all over the world. Potentially, proton therapy (but not ion therapy) may prove better than any other radiation therapy, since with better tolerance the dose load can probably be reduced. Because of the great uncertainty prevailing, no attempt has been made to estimate the number of patients, and post-operative radiation therapy has yet to be accepted as routine treatment in Sweden.

Palliation

It is estimated that approximately 90 patients in need of palliation from an advanced malignant tumour should be offered symptom relief with proton therapy within the framework of clinical studies if such treatment was available in Sweden. The potential benefits of such treatment are a reduction of the acute side-effects and the possibility of improved quality of life.

Discussion

Since protons interact with tissues in much the same way as photons and electrons but with better dose distribution, it is arguable that they are virtually always at least as good as conventional radiation therapy. If the tissue surrounding the tumour is highly heterogeneous and is liable to vary, e.g. different quantities of air, there is some risk of protons giving a less certain and, consequently, inferior dose distribution in a few cases. Further, the skin-sparing effect of proton beams is less than that of photon beams, which may be of clinical importance in some instances for the cosmetic results. Since, on the other hand, protons are hardly ever inferior but can only be better, it is arguable that, if supply and cost were equal, protons would generally be used instead of photons and electrons. Thus the potential number of patients is the same as the majority of patients treated with external radiation therapy.

Since proton facility investments will always be higher and the cost of running the treatments probably also somewhat higher (it remains uncertain

by how much, especially as compared with IMRT), the cost in relation to the potential gains, i.e. cost-effectiveness, must always decide which patients protons are indicated for [38–41]. Because our knowledge of cost-effectiveness is limited, all estimates of the proportion of potentially eligible patients will be very tentative. There is no sound knowledge of what is cost-effective, and so all assessments are open to criticism. Our premises are based on the point at which we believe the medical profession will find the potential benefits great enough to justify the extra trouble and expenses entailed by "sending patients for proton therapy in a national facility".

Similar attempts to estimate the number of patients suitable for hadrons (protons and ions, generally not separated in the studies) therapy have likely been performed by several groups prior to decisions to proceed with the process towards realisation of a treatment facility. Three such investigations have been performed in other European countries and, at least partly, published.

The Centro Nazionale Adroterapia Oncologica (CNAO) separated patients for whom hadron therapy was indicated into two categories. Category A included all tumours in which the use of proton therapy had clearly demonstrated superiority and category B tumours where improved locoregional control, possible with protons, likely would result in more patients cured. The study was originally published in 1998 [42] and updated, based upon more recent statistics and knowledge, in 2004 [43]. According to the update, 830 patients, constituting 44% of the number of patients with these diagnoses in Italy per year were candidates for elective proton therapy (category A) and more than 15 000 patients (13% of the population) for therapy in clinical trials (category B). It was totally estimated that about 16% of the irradiated patients were candidates for proton therapy. The most common diagnoses in category A (corresponding to those listed in the upper part of Table I) were uveal melanomas, paranasal sinus tumours and meningeomas of the base of the skull. In category B (middle, lower part of Table I), prostate cancer constitutes the largest group (5600 patients, 25% of irradiated patients) followed by pancreatic cancer (1800, 20%), bladder carcinoma (1700, 10%), lung cancer (1550, 5%), liver cancer (1300, 10%) and head and neck tumours (1000, 15%). In the update, an estimate was also made for the number of Italian patients eligible for carbon ion therapy of those eligible for proton therapy. About 3700, or between 3000–4000 patients, were considered as such candidates, constituting 23% of those considered candidates for proton therapy (5% of all irradiated patients). Lung cancer (1550 patients) followed by prostate cancer (1100 patients) and liver cancer (500 patients) were the most common diagnoses.

The French ETOILE project made a "one day survey" at five university hospitals, identifying 77 patients, mainly head and neck cancers (n = 31), gliomas (n = 8), lung cancer (n = 6), uterus (n = 5), gastric (n = 5) and prostate (n = 3), being potential candidates for hadron therapy. This figure constituted 14.5% of the number of patients irradiated. Extrapolated to 160 000 irradiated patients per year in France, 23 000 were potential candidates for hadron (proton or carbon) therapy each year [44].

A nationwide Austrian survey (MedAustron) identified all new patients starting radiotherapy during a three months period. It was then estimated that about 2000 patients, representing 5.6% of all newly diagnosed cancer patients and 13.5% of all irradiated cancer patients, were candidates for hadron (proton and ions) therapy [45]. The most common diagnoses suitable were prostate cancer (470 patients, 29% of all irradiated), head and neck tumours (251, 25%) and lung cancer (239, 27%). Primary breast cancer was not considered a candidate.

Thus we find that this Swedish study and three separate other European investigations, having very different designs, reach the conclusion that between 13–16% of all irradiated patients are suitable for proton therapy. A proportion of these, not always accurately estimated, are also suitable for ion therapy. Ideally, any estimate of the potential number of patients for a new treatment should be made by a prospective assessment during a prolonged time period. Although the figures reached in such a recording can always be criticized, since there is no clear definitions of what criteria are set for an improvement (higher TCP and/or lower NTCP) of such a magnitude that the increased costs are motivated, this was done in the MedAustron project. In order to get a reasonable estimate also of uncommon tumour types, frequently suitable for proton therapy, the estimates must be made during a prolonged time period. In this respect, three months appears reasonable. The French investigation was also made after a prospective assessment, but only of one day's duration, which makes all estimations very unreliable. The SPTC estimate was based upon a recording of all irradiated patients within the SBU report [37], but the estimations of the number of patients eligible for proton therapy was made retrospectively, based upon a literature review. In the evaluations of the potential value of proton beams for improved tumour control, we considered the SBU-estimations of gains after dose escalation [46].

Given the lack of relevant clinical information for most tumour types, we also evaluated the results of

dose-planning model studies. Similar to the differences in scientific quality between clinical trials with different designs and performance, these model studies can also be conducted with varying quality [47]. The physical evaluations can only provide an idea of whether one technique confers dose distribution advantages over another, but cannot tell how much better one treatment can be. This is possible using biological models, but, since knowledge of the size of the coefficients in the different models still is limited, these estimations must be carefully interpreted [48,49]. Relative differences between different techniques are probably more robust than absolute differences. However, absolute differences are fundamental in order to evaluate the potential number of patients gaining sufficiently from a new treatment. Due to the variability between patients and tumours, it is then necessary to include and plan several patients in order to arrive at a reasonable estimate of the absolute differences. This has rarely been done (Table II). The body of evidence from the literature that proton beams confer physical dose distribution advantages is at present so extensive that further studies provide only limited new information. Rather, they must focus on the absolute gains from proton beams to aid in the decision of what clinical study designs should be used and in the dimension of the randomized trials.

Protons or ions?

The capacity of protons and ions for improving cancer treatment has been a topic of widespread discussions in Sweden and elsewhere in recent years. These discussions have also proceeded within the Swedish Proton Therapy Centre (SPTC) project. No further description of the arguments for and against one or the other kind of radiation will be presented here. Instead, we refer to the report published by the Swedish Cancer Society [49] and to the Proceedings of the heavy charged particles in Biology and Medicine (HCPBM) and ENLIGHT meetings in Baden and Lyon, published in a supplement of Radiotherapy and Oncology in December 2004 [50].

Our primary concern being to show in clinical studies whether particle radiation offers such great therapeutic advantages that it should be part of the routine care of cancer patients, protons are the natural choice. Proton therapy is already a practical clinical treatment for a number of tumour indications, and clinical experience of proton therapy greatly exceeds that of light ion therapy. We consider that the use of ions presently is clinically immature. Furthermore, a proton therapy facility is to a great extent based on proven technology and systematically co-ordinated individual main components. The great difference today between proton and light ion radiation is perhaps one of facility design and operational dependability. It is reasonable to assume that necessary clinical studies, prompted for example by the great explosion of knowledge in imaging techniques, cell-, tumour- and molecular biology, can be started and completed much faster with protons than with ions.

Ions, with their high LET (linear energy transfer) component, offer potential advantages in the treatment of hypoxic and slow-growing, radiation-resistant tumours [8]. The physical advantages of ions (sharper penumbras at greater depths) over protons are probably limited and are unlikely ever to be a sole reason for the choice of ions rather than protons [52]. The biological consequences of the high LET of light ions make it of scientific interest to explore, in greater depths, the possibilities of ions improving treatment outcomes. In the long term it is very interesting to carry out comparable clinical studies of protons and ions. This is also the focus of the facility under construction in Heidelberg, Germany [51].

Given our great uncertainties concerning the relative biological effect of different parts of the ion beam, as well as the other biological effects of the high LET component, it is very hard to judge the number of cases in which ions are potentially better than protons. Light ions are contraindicated for some tumour sites, for example, for virtually all pediatric tumours, for AVMs, and for sites where the tumour is intimately connected to sensitive tissues, like oesophagus and other parts of the gastrointestinal tract, pancreas, and urinary bladder, whose preservation is important. The three estimates performed in Austria, France and Italy have considered the use of both protons and ions, but with the exception of the Italian study [43], the published material has not been detailed enough to estimate what proportion would do sufficiently better with ions than with protons. The investigations have, however, resulted in decisions to invest in combined proton and ion facilities in Vienna, Austria (MedAustron) [53], Pavia, Italy (TERA/CNAO project) [54], and Lyon, France (ETOILE) [55] within the ENLIGHT project.

Development of methods of diagnosis and tumour characterisation

Adequate delineation of tumour extent is fundamental to all radiation therapy. The requirements in this respect do not differ essentially from those for other advanced (locally) curative radiation treatment. Since, however, protons (and ions) confer very good possibilities of saving adjacent normal

tissue; the diagnostic requirements must be very high and at least on a par with those indicated by the world's leading centres. The Cancer Society, in its report on radiation therapy research in Sweden, has referred to problems with tumour imaging in Sweden [56]. Regardless of whether a proton therapy facility is built in Sweden, local tumour diagnosis needs to be reviewed and necessary improvements made. A national proton therapy facility will provide a strong incentive for co-ordinating this on a national basis. Given the purpose of most patients being examined and their treatment fully planned at their (university) home clinic, all equipment and competence must in principle be universally available.

Future development of image-based adapted radiotherapy

The possibilities of PET for staging and target definition are currently under discussion [57,58], and it seems reasonable to suppose that PET is at least superior to other staging methods for several diagnoses. Although certain studies assert that targets can be drawn better, either smaller or larger, with PET in connection, for example, with ear, nose and throat tumours and lung cancer, it is still unclear whether this entails a better treatment outcome. The importance of PET and magnetic resonance imaging (MRI) for target drawing must be studied further, primarily in prospective studies. The potential of PET, MRI and other techniques for revealing areas of the tumour which require deviations from the usual mean dosage must be investigated more closely. There is a need here for more research in Sweden, research which the proton therapy initiative may serve to accelerate.

Clinical therapy research

One express purpose of the dedicated proton beam therapy facility is to show in clinical studies how great are the advantages of protons compared to conventional radiation. The aim is to treat the majority or at least 80% of Swedish patients in clinical prospective protocols. We have identified the need of clinical therapy research for each diagnosis separately and have also briefly described suitable study designs. In certain cases randomized studies are desirable and necessary in which proton therapy, partly or completely, is one experimental arm, compared with a control arm without protons. In other case randomization can take place between protons only or as a boost treatment, or alternatively with different proton dose levels etc. There are many cases where randomized studies are neither necessary nor possible. For these cases, prospective protocols are to be drawn up in which staging and the implementation and follow-up of therapy are defined and subjected to research-ethical review. Protocols of this kind are to be drawn up for the majority of clinical situations which can come into question for proton therapy. There will always be unusual cases where a clinical study is not feasible, e.g. extremely uncommon forms of tumour, reirradiations and special cases due to anatomical idiosyncrasy.

The Swedish Health Care system is well suited for this type of clinical trials as all citizens are fully covered by the national social security system. Patient selection will thus be based solely on clinical and scientific grounds. Efficient inclusion of patients and complete follow-up will further be secured by the planned infrastructure of the SPTC where all planning and full responsibility for the patient will remain with the regional university hospitals. Only the actual proton beam treatment will be performed at SPTC.

It is assumed that the studies will be worked out through discussions on a national (Nordic) basis, e.g. under the aegis of regional/national therapy programme groups or the planning groups supported by the Swedish Cancer Society. Mandators and peer assessors for the studies comprise those who are most interested in and suited to this function. It is hoped that responsibility for the studies and their implementation will be decentralised in Sweden, according to the research interest and competence existing.

Conclusions

After an extensive literature review, including clinical trials and model dose planning studies, it is estimated that in Sweden between 2200 and 2500 patients annually are eligible for proton beam therapy. For these patients, the potential therapeutic benefit appears to be so great as to justify the additional expense of proton beam therapy. The assessed number constitutes between 14–15% of all irradiated patients annually. Similar proportions have been reached in three other similar European investigations. Even if these four, very differently designed investigations, reached the same overall results (13–16%), major differences were found though, regarding which patient subgroups would benefit the most. These discrepancies can only be resolved in properly designed clinical trials.

A facility based on the SPTC-concept, with a distributed logistics and expert support, will offer a unique base for conclusive randomized clinical trials. Inclusion of patients in the trials will not depend on individual economical input. Further, general access

to this type of high precision therapy for all university hospitals will accelerate research in image-based individualisation of cancer therapy.

The present estimations of patients suitable for proton therapy are based on a large collection of calculations and clinical experience. Future research and development in a dedicated clinical proton facility will hopefully result in more individually adapted high precision therapy based on verified clinical evidence.

References

[1] Hellman S. Technology, biology and traffic. Acta Oncol 2001;40:679–81.

[2] Mattsson S, Brahme A, Carlsson J, Denekamp J, Forsell-Aronsson E, Hellström M, et al. Swedish Cancer Society radiation therapy research investigation. Acta Oncol 2002; 41:596–603.

[3] World Health Organization. www.who.int/mediacentre/news/releases/2003/pr27/en.

[4] Norlund A. Costs of radiotherapy. Acta Oncol 2003;42: 411–5.

[5] Yuh GE, Loredo LN, Yonemoto LT, Bush DA, Shahnazi K, Preston W, et al. Reducing toxicity from craniospinal irradiation: using proton beams to treat medulloblastoma in young children. Cancer J 2004;10:386–90.

[6] Bentzen SM. High-tech in radiation oncology: should there be a ceiling? Int J Radiat Oncol Biol Phys 2004;58:320–30.

[7] Johansson KA, Mattsson S, Brahme A, Carlsson J, Zackrisson B, Turesson I, et al. Radiation therapy dose delivery. Acta Oncol 2003;42:85–91.

[8] Turesson I, Johansson K-A, Mattsson M. The potential of proton and light ion beams in radiotherapy. Acta Oncol 2003;42:107–14.

[9] Glimelius B, Steineck G. Low evidence of radiation therapy in prostate cancer-a plea for intensified scientific activity. Acta Oncol 2004;43:311–5.

[10] Bentzen SM. From clincal trials to clinical practice: A user's guide to evidence-based oncology. Eur J Cancer Suppl 2003;1:77–91.

[11] Sisterson J. World-wide charged particle patient totals. July 2005. Particles 2005;33:11.

[12] Egger E, Zografos L, Schalenbourg A, Beati D, Bohringer T, Chamot L, et al. Eye retention after proton beam radiotherapy for uveal melanoma. Int J Radiat Oncol Biol Phys 2003;55:867–80.

[13] Noel G, Habrand JL, Mammar H, Pontvert D, Haie-Meder C, Hasboun D, et al. Combination of photon and proton radiation therapy for chordomas and chondrosarcomas of the skull base: the Centre de Protontherapie D'Orsay experience. Int J Radiat Oncol Biol Phys 2001;51:392–8.

[14] Suit H, Goldberg S, Niemierko A, Trofimov A, Adams J, Paganetti H, et al. Proton beams to replace photon beams in radical dose treatments. Acta Oncol 2003;42:800–8.

[15] Goodman C. Literature searching and evidence interpretation for assessing health care practices. Swedish Council on Technology Assessment in Health Care. Stockholm: Norstedts; 1993. p. 81.

[16] Ringborg U, Bergqvist D, Brorsson B, Cavallin-Ståhl E, Ceberg J, Einhorn N, et al. The Swedish Council on technology assessment in health care (SBU) systematic overview of radiotherapy for cancer including a prospective survey of radiotherapy practice in Sweden – 2001 summary and conclusions. Acta Oncol 2003;42:357–65.

[17] Foroudi F, Tyldesley S, Barbera L, Huang J, Mackillop WJ. Evidence-based estimate of appropriate radiotherapy utilization rate for prostate cancer. Int J Radiat Oncol Biol Phys 2003;55:51–63.

[18] Foroudi F, Tyldesley S, Barbera L, Huang J, Mackillop WJ. An evidence-based estimate of the appropriate radiotherapy utilization rate for colorectal cancer. Int J Radiat Oncol Biol Phys 2003;56:1295–307.

[19] Foroudi F, Tyldesley S, Walker H, Mackillop WJ. An evidence-based estimate of appropriate radiotherapy utilization rate for breast cancer. Int J Radiat Oncol Biol Phys 2002;53:1240–53.

[20] Tyldesley S, Boyd C, Schulze K, Walker H, Mackillop WJ. Estimating the need for radiotherapy for lung cancer: an evidence-based, epidemiologic approach. Int J Radiat Oncol Biol Phys 2001;49:973–85.

[21] Nilsson S, Widmark A, Norlén BJ. A systematic overview of radiation therapy effects in prostate cancer. Acta Oncol 2004;43:316–81.

[22] Zackrisson B, Mercke C, Strander H, Wennerberg J, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in head and neck cancer. Acta Oncol 2003;42:443–61.

[23] Ask A, Albertsson M, Järhult J, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in oesophageal cancer. Acta Oncol 2003;42:462–75.

[24] Glimelius B, Grönberg H, Järhult J, Wallgren A, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in rectal cancer. Acta Oncol 2003;42:476–92.

[25] Sirzén F, Kjellen E, Sörenson S, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in non-small cell lung cancer. Acta Oncol 2003;42:493–515.

[26] Strander H, Turesson I, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in soft tissue sarcomas. Acta Oncol 2003;42:516–31.

[27] Rutqvist LE, Rose C, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in breast cancer. Acta Oncol 2003;42:532–45.

[28] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in uterine cancer (corpus uteri). Acta Oncol 2003;42:557–61.

[29] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in ovarian cancer. Acta Oncol 2003;42: 562–6.

[30] Einhorn N, Trope C, Ridderheim M, Boman K, Sorbe B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in cervical cancer (cervix uteri). Acta Oncol 2003;42:546–56.

[31] Widmark A, Flodgren P, Damber J, Hellsten S, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in urinary bladder cancer. Acta Oncol 2003;42:567–81.

[32] Berg G, Blomquist E, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in brain tumours. Acta Oncol 2003;42:582–8.

[33] Gustavsson A, Osterman B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in non-Hodgkin's lymphoma. Acta Oncol 2003;42:605–19.

[34] Gustavsson A, Osterman B, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in Hodgkin's lymphoma. Acta Oncol 2003;42:589–604.

[35] Falkmer U, Järhult J, Wersäll P, Cavallin-Ståhl E. A systematic overview of radiation therapy effects in skeletal metastases. Acta Oncol 2003;42:620–33.

[36] Bentzen SM, Heeren G, Cottier B, Slotman B, Glimelius B, Lievens Y, et al. Towards evidence-based guidelines for radiotherapy infrastructure and staffing needs in Europe: the ESTRO QUARTS project. Radiother Oncol 2005;75: 355–65.

[37] Möller TR, Brorsson B, Ceberg J, Frodin JE, Lindholm C, Nylen U, et al. A prospective survey of radiotherapy practice 2001 in Sweden. Acta Oncol 2003;42:387–410.

[38] Lundkvist J, Ekman M, Rehn Ericsson S, Isacsson U, Jönsson B, Glimelius B. Economic evaluation of proton radiation therapy in the treatment of breast cancer. Radiother Oncol 2005;75:179–85.

[39] Lundkvist J, Ekman M, Rehn Ericsson S, Jönsson B, Glimelius B. Proton therapy of cancer: Potential clinical advantages and cost-effectiveness. Acta Oncol 2005;44: 850–61.

[40] Lundkvist J, Ekman M, Rehn Ericsson S, Jönsson B, Glimelius B. Cost-effectiveness of proton radiation in the treatment of childhood medulloblastoma. Cancer 2005; 103:793–801.

[41] Lievens Y, Van den Bogaert W. Proton beam therapy: too expensive to become true? Radiother Oncol 2005;75: 131–3.

[42] Orrecchia R, Krengli M. Number of potential patients to be treated with proton therapy in Italy. Tumori 1998;84: 205–8.

[43] Krengli M, Orecchia R. Medical aspects of the National Centre for Oncological Hadrontherapy (CNAO-Centro Nazionale Adroterapia Oncologica) in Italy. Radiother Oncol 2004;73(Suppl 2):21–8.

[44] Baron MH, Pommier P, Favrel V, Truc G, Balosso J, Rochat J. A "one-day survey": As a reliable estimation of the potential recruitment for proton- and carbon-ion therapy in France. Radiother Oncol 2004;73(Suppl 2): 15–7.

[45] Mayer R, Mock U, Jäger R, Pötter R, Vutuc C, Eiter H, et al. Epidemiological aspects of hadron therapy: A prospective nationwide study of the Austrian project MedAustron and the Austrian Society of Radiooncology (OEGRO). Radiother Oncol 2004;73(Suppl 2):24–8.

[46] Svensson H, Möller T. Developments in radiotherapy. Acta Oncol 2003;42:430–42.

[47] Glimelius B, Isacsson U, Blomquist E, Grusell E, Jung B, Montelius A. Potential gains using high-energy protons for therapy of malignant tumours. Acta Oncol 1999;38:137–45.

[48] Zackrisson B, Mattsson S, Kjellén E, Glimelius B, Swedish Cancer Society Investigation Group. Research and development of radiation therapy in clinical routines. Acta Oncol 2003;42:115–22.

[49] Turesson I, Carlsson J, Brahme A, Glimelius B, Zackrisson B, Stenerlow B, et al. Biological response to radiation therapy. Acta Oncol 2003;42:92–106.

[50] Proceedings of the heavy charged particles in Biology and Medicine (HCPBM) and ENLIGHT meetings in Baden and Lyon. Amaldi U, Auberger T, Debus J, Francois G, Gerard JP, Heeren G, et al, editors. Radiother Oncol 2004;73(Suppl 2):S1–S217.

[51] Haberer T, Debus J, Eickhoff H, Jakel O, Schulz-Ertner D, Weber U. The Heidelberg Ion Therapy Center. Radiother Oncol 2004;73(Suppl 2):S186–90.

[52] Weyrather WK, Debus J. Particle beams for cancer therapy. Clin Oncol (R Coll Radiol) 2003;15:S23–8.

[53] Griesmayer E, Auberger T. The status of MedAustron. Radiother Oncol 2004;73(Suppl 2):S202–5.

[54] Amaldi U. CNAO–The Italian Centre for Light-Ion Therapy. Radiother Oncol 2004;73(Suppl 2):S191–201.

[55] Bajard M, De Conto JM, Remillieux J. Status of the "ETOILE" project for a French hadrontherapy centre. Radiother Oncol 2004;73(Suppl 2):S211–5.

[56] Forssell-Aronsson E, Kjellén E, Mattsson S, Hellström M, Swedish Cancer Society Investigation Group.. Medical imaging for improved tumour characterisation, delineation and treatment verification. Acta Oncol 2002;41:604–14.

[57] Gregoire V. Is there any future in radiotherapy planning without the use of PET: unraveling the myth. Radiother Oncol 2004;73:261–3.

[58] Facey K, Bradbury I, Laking G, Payne E. Positron Emission Tomography (PET) in Cancer Management. Health Technology Assessment, NHS R&D HTA Programme July 2004.

[59] Suit HD, Becht J, Leong J, Stracher M, Wood WC, Verhey L, et al. Potential for improvement in radiation therapy. Int J Radiat Oncol Biol Phys 1988;14:777–86.

[60] Brown AP, Urie MM, Chisin R, Suit HD. Proton therapy for carcinoma of the nasopharynx: a study in comparative treatment planning. Int J Radiat Oncol Biol Phys 1989;16: 1607–14.

[61] Urie MM, Goitein M. Variable versus fixed modulation of proton beams for treatments in the cranium. Med Phys 1989;16:593–601.

[62] Austin-Seymour M, Urie M, Munzenrider J. Considerations in fractionated proton radiation therapy: clinical potential and results. Radiother Oncol 1990;17:29–35.

[63] Tatsuzaki H, Urie MM, Willett CG. 3-D comparative study of proton vs. x-ray radiation therapy for rectal cancer. Int J Radiat Oncol Biol Phys 1992;22:369–74.

[64] Archambeau JO, Slater JD, Slater JM, Tangeman R. Role for proton-beam irradiation in treatment of peciatric CNS malignancies. Int J Radiat Oncol Biol Phys 1992;22: 287–94.

[65] Gademann G, Wannenmacher M. Charged particle therapy to pediatric tumors of the retroperitoneal region: a possible indication. Int J Radiat Oncol Biol Phys 1992;22:375–81.

[66] Levin CV. Potential for gain in the use of proton-beam boost to the para-aortic lymph nodes in carcinoma of the cervix. Int J Radiat Oncol Biol Phys 1992;22:355–60.

[67] Miralbell R, Crowell C, Suit HD. Potential improvement of three dimension treatment planning and proton therapy in the outcome of maxillary sinus cancer. Int J Radiat Oncol Biol Phys 1992;22:305–10.

[68] Slater JM, Slater JD, Archambeau JO. Carcinoma of the tonsillar region: potential for use of proton-beam therapy. Int J Radiat Oncol Biol Phys 1992;22:311–9.

[69] Smit B. Prospects for proton therapy in carcinoma of the cervix. Int J Radiat Oncol Biol Phys 1992;22:349–54.

[70] Tatsuzaki H, Gregoire V, Linggood R. Comparative treatment planning: proton vs x-ray beams against glioblastoma multiforme. Int J Radiat Oncol Biol Phys 1992;22:265–74.

[71] Wambersie A, Gregroire V, Brucher JM. Potential clinical gain of proton (and heavy ion) beams for brain tumors in children. Int J Radiat Oncol Biol Phys 1992;22:275–86.

[72] Miralbell R, Urie M. Potential improvement of three dimension treatment planning and proton beams in fractionated radiotherapy of large cerebral arteriovenous malformations. Int J Radiat Oncol Biol Phys 1993;25:353–8.

[73] Lee M, Wynne C, Webb S, Nahum AE, Dearnaley D. A comparison of proton and megavoltage X-ray treatment planning for prostate cancer. Radiother Oncol 1994;33: 239–53.

[74] Isacsson U, Montelius A, Jung B, Glimelius B. Comparative treatment planning between proton and x-ray therapy in locally advanced rectal cancer. Radiother Oncol 1996;41: 263–72.

[75] Isacsson U, Hagberg H, Johansson KA, Montelius A, Jung B, Glimelius B. Potential advantages of protons over conventional radiation beams for paraspinal tumours. Radiother Oncol 1997;45:63–70.

[76] Miralbell R, Lomax A, Bortfeld T, Rouzaud M, Carrie C. Potential role of proton therapy in the treatment of pediatric medulloblastoma/primitive neuroectodermal tumors: reduction of the supratentorial target volume. Int J Radiat Oncol Biol Phys 1997;38:477–84.

[77] Miralbell R, Lomax A, Russo M. Potential role of proton therapy in the treatment of pediatric medulloblastoma/primitive neuro-ectodermal tumors: spinal theca irradiation. Int J Radiat Oncol Biol Phys 1997;38:805–11.

[78] Sandison GA, Papiez E, Bloch C, Morphis J. Phantom assessment of lung dose from proton arc therapy. Int J Radiat Oncol Biol Phys 1997;38:891–7.

[79] Isacsson U, Lennernäs B, Grusell E, Jung B, Montelius A, Glimelius B. Comparative treatment planning between proton and x-ray therapy in esophageal cancer. Int J Radiat Oncol Biol Phys 1998;41:441–50.

[80] Verhey LJ, Smith V, Serago CF. Comparison of radiosurgery treatment modalities based on physical dose distributions. Int J Radiat Oncol Biol Phys 1998;40:497–505.

[81] Fuss M, Hug EB, Schaefer RA, Nevinny-Stickel M, Miller DW, Slater JM, et al. Proton radiation therapy (PRT) for pediatric optic pathway gliomas: comparison with 3D planned conventional photons and a standard photon technique. Int J Radiat Oncol Biol Phys 1999;45:1117–26.

[82] Lee C, Tait D, Nahum A, Webb S. Comparison of proton therapy and conformal x-ray therapy in non-small cell lung cancer (NSCLC). Br J Radiat 1999;72:1078–84.

[83] Lomax A. Intensity modulation methods for proton radiotherapy. Phys Med Biol 1999;44:185–205.

[84] Lomax AJ, Bortfeld T, Goitein G, Debus J, Dykstra C, Tercier PA, et al. A treatment planning inter-comparison of proton and intensity modulated photon radiotherapy. Radiother Oncol 1999;51:257–71.

[85] Fuss M, Poljanc K, Miller DW, Archambeau JO, Slater JM, Slater JD, et al. Normal tissue complication probability (NTCP) calculations as a means to compare proton and photon plans and evaluation of clinical appropriateness of calculated values. Int J Cancer 2000;90:351–8.

[86] Lin R, Hug EB, Schaefer RA, Miller DW, Slater JM, Slater JD. Conformal proton radiation therapy of the posterior fossa: a study comparing protons with three-dimensional planned photons in limiting dose to auditory structures. Int J Radiat Oncol Biol Phys 2000;48:1219–26.

[87] Miralbell R, Cella L, Weber D, Lomax A. Optimizing radiotherapy of orbital and paraorbital tumors: intensity-modulated X-ray beams vs. intensity-modulated proton beams. Int J Radiat Oncol Biol Phys 2000;47:1111–9.

[88] Oelfke U, Bortfeld T. Intensity modulated radiotherapy with charged particle beams: studies of inverse treatment planning for rotation therapy. Med Phys 2000;27:1246–57.

[89] Paulino AC, Wen BC, Brown CK, Tannous R, Mayr NA, Zhen WK, et al. Late effects in children treated with radiation therapy for Wilms' tumor. Int J Radiat Oncol Biol Phys 2000;46:1239–46.

[90] Smith AR, Loeffler JS, Adams JA, Lomax AJ, Niemierko A. The potential for proton therapy to improve clinical outcomes: Comparisons of proton and x-ray treatment plans for the purpose of tumor dose escalation and/or reduction of treatment-related morbidity. Int J Radiat Oncol Biol Phys 2000;48(Suppl 338 abstr 2150).

[91] Zurlo A, Lomax A, Hoess A, Bortfeld T, Russo M, Goitein G, et al. The role of proton therapy in the treatment of large irradiation volumes: a comparative planning study of pancreatic and biliary tumors. Int J Radiat Oncol Biol Phys 2000;48:277–88.

[92] Baumert BG, Lomax AJ, Miltchev V, Davis JB. A comparison of dose distributions of proton and photon beams in stereotactic conformal radiotherapy of brain lesions. Int J Radiat Oncol Biol Phys 2001;49:1439–49.

[93] Cella L, Lomax A, Miralbell R. Potential role of intensity modulated proton beams in prostate cancer radiotherapy. Int J Radiat Oncol Biol Phys 2001;49:217–23.

[94] Cozzi L, Fogliata A, Lomax A, Bolsi A. A treatment planning comparison of 3D conformal therapy, intensity modulated photon therapy and proton therapy for treatment of advanced head and neck tumours. Radiother Oncol 2001;61:287–97.

[95] Johansson J, Isacsson U, Lindman H, Montelius A, Glimelius B. Node-positive left-sided breast cancer patients after breast-conserving surgery: potential outcomes of radiotherapy modalities and techniques. Radiother Oncol 2002;65:89–98.

[96] Miralbell R, Lomax A, Cella L, Schneider U. Potential reduction of the incidence of radiation-induced second cancers by using proton beams in the treatment of pediatric tumors. Int J Radiat Oncol Biol Phys 2002;54:824–9.

[97] Bolsi A, Fogliata A, Cozzi L. Radiotherapy of small intracranial tumours with different advanced techniques using photon and proton beams: a treatment planning study. Radiother Oncol 2003;68:1–14.

[98] Lomax AJ, Cella L, Weber D, Kurtz JM, Miralbell R. Potential role of intensity-modulated photons and protons in the treatment of the breast and regional nodes. Int J Radiat Oncol Biol Phys 2003;55:785–92.

[99] Lomax AJ, Goitein M, Adams J. Intensity modulation in radiotherapy: photons versus protons in the paranasal sinus. Radiother Oncol 2003;66:11–8.

[100] Johansson J, Blomquist E, Montelius A, Isacsson U, Glimelius B. Potential outcomes of modalities and techniques in radiotherapy for patients with hypopharyngeal carcinoma. Radiother Oncol 2004;72:129–38.

[101] Mock U, Georg D, Bogner J, Auberger T, Potter R. Treatment planning comparison of conventional, 3D conformal, and intensity-modulated photon (IMRT) and proton therapy for paranasal sinus carcinoma. Int J Radiat Oncol Biol Phys 2004;58:147–54.

[102] St Clair WH, Adams JA, Bues M, Fullerton BC, La Shell S, Kooy HM, et al. Advantage of protons compared to conventional X-ray or IMRT in the treatment of a pediatric patient with medulloblastoma. Int J Radiat Oncol Biol Phys 2004;58:727–34.

[103] Weber DC, Trofimov AV, Delaney TF, Bortfeld T. A treatment planning comparison of intensity modulated photon and proton therapy for paraspinal sarcomas. Int J Radiat Oncol Biol Phys 2004;58:1596–606.

[104] Yock TI, Tarbell NJ. Technology insight: proton beam radiotherapy for treatment in pediatric brain tumours. Review. Nat Clin Pract Oncol 2004;1:97–103.

[105] Krengli M, Hug EB, Adams JA, Smith AR, Tarbell NJ, Munzenrider JE. Proton radiation therapy for retinoblastoma: comparison of various intraocular tumor locations and beam arrangements. Int J Radiat Oncol Biol Phys 2005;61:583–93.

[106] Mu X, Björk-Eriksson T, Nill S, Oelfke U, Johansson K-A, Gagliardi G, et al. Does electron and proton therapy reduce the risk for late-effects after spinal irradiation for childhood medulloblastoma?-A comparative treatment planning study. Acta Oncol 2005;44:554–62.

Delivering Growth and Value in Cancer by Integrating Care Across the Continuum

Trever Burgon, PhD
Director, Sg2

Agenda

Growth in the Volume to Value…to Volume Era

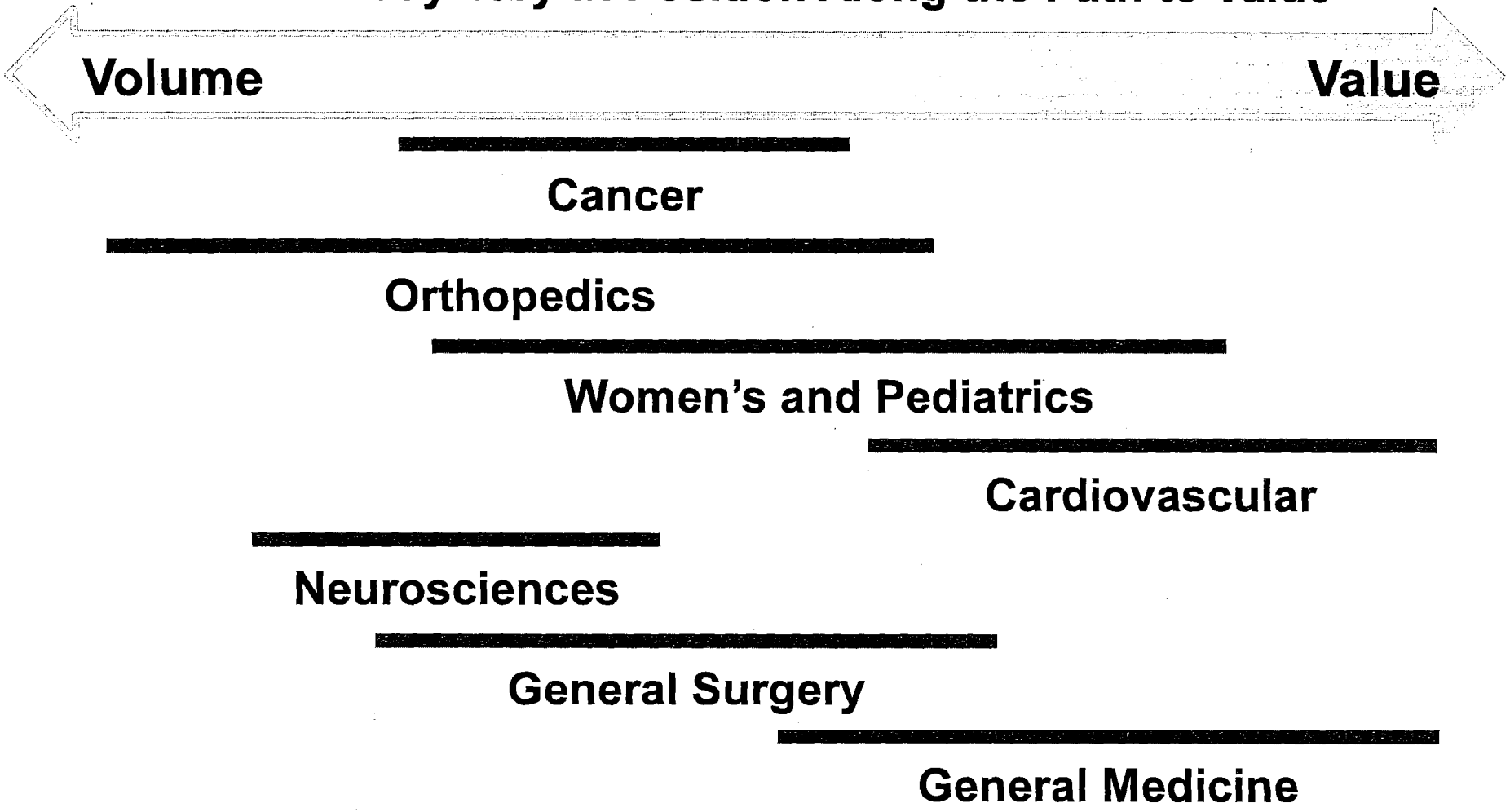
2012 Inpatient and Outpatient Cancer Forecast

Tumor-Specific Growth Opportunities

Building a Coordinated, Aligned Cancer Program

Common Themes Force All Service Lines to Shift Focus to Value

Service Lines Today Vary in Position Along the Path to Value



health care intelligence

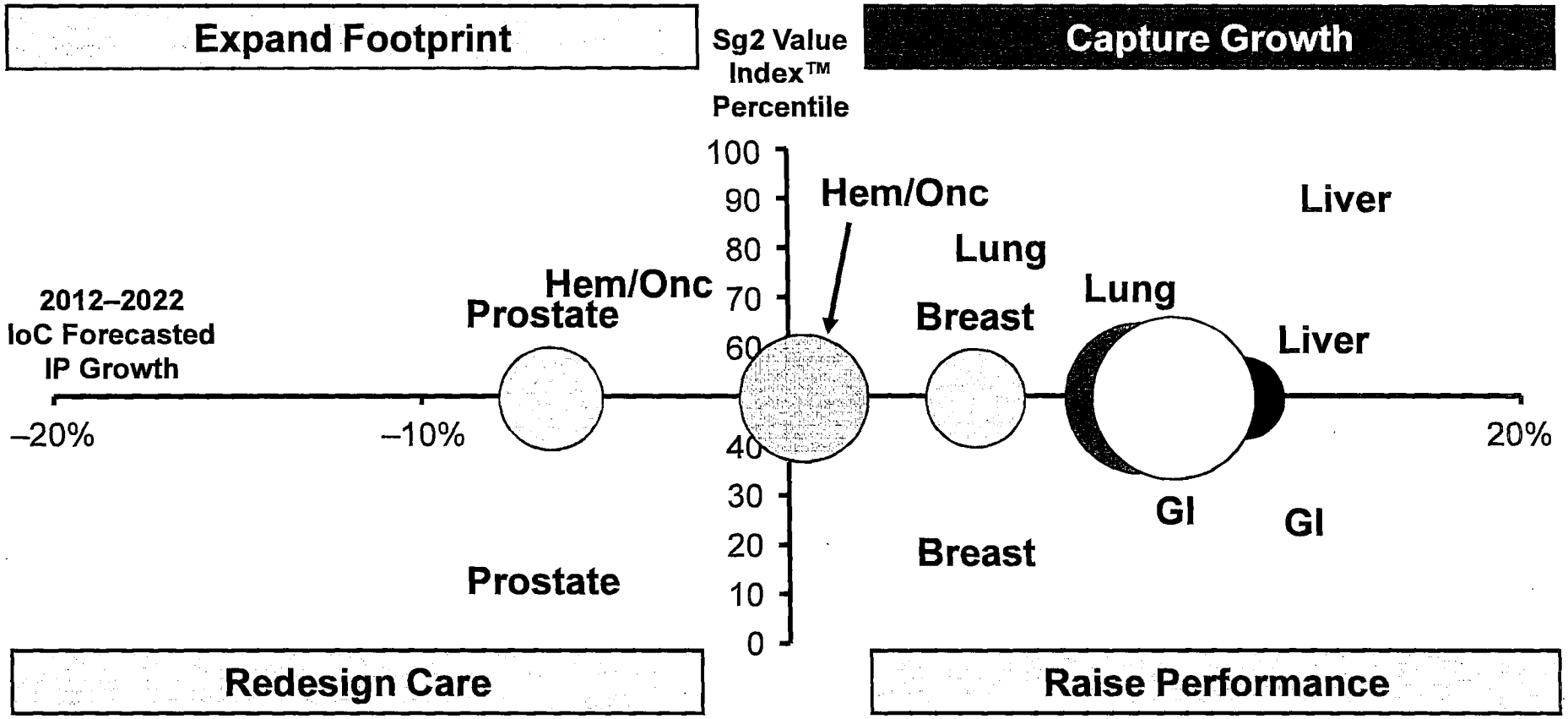
Most Cancer Care Remains Fee-for-Service, but Payment Changes Are Here

New Payment Model	Program Description	Example Programs	
		Provider(s)	Payer
Bundled Payment: Chemotherapy	Case management fee and up-front payment for course of chemotherapy	Five oncology practices (TX, OH, MO, GA, TN)	United Healthcare
Bundled Payment: Radiation Oncology	Single payment for radiation therapy services for 13 most-common cancer diagnoses	21st Century Oncology	Humana
Oncology Medical Home	Increased reimbursement based on demonstrated cost and quality goals	Wilshire Oncology	Anthem BCBS WellPoint
Oncology ACO	Shared savings for all cancer services delivered for 6 most-common tumor types	▪ Baptist Health South Florida ▪ Advanced Medical Specialties	Florida Blue

BCBS = Blue Cross Blue Shield. Sources: Mass A. Florida Blue teams with hospital system, oncologists to form cancer-focused ACO. *Health Business Daily* June 11, 2012; UnitedHealth Group. New UnitedHealthcare cancer care payment model to focus on best treatment practices and better health outcomes [press release]. www.unitedhealthgroup.com/newsroom/news.aspx?id=efeefe23-c20a-47b1-ad72-73bba875d46c. Published October 20, 2010; Tocknell M. Humana, FL physicians group bundle radiation services. Health Leaders Media. August 15, 2012; Bosserman L. Oncology medical home payer negotiations for CA OMP pilot. Presented at: 2011 Cancer Center Business Summit, October 2011, Chicago, IL; Association for Value-Based Cancer Care. Wilshire Oncology medical home pilot: reengineering cancer care. www.valuebasedcancer.com/article/wilshire-oncology-medical-home-pilot-reengineering-cancer-care; All Web sites accessed August 2012.

Capturing Growth Will Depend on Proving Performance and Value

Sample Large Community Hospital: Inpatient Cancer Service Line



Note: Bubble size represents 2012 discharge volume. All data show a sample hospital's performance plotted against Sg2's national growth forecast.
Forecast analysis excludes ages 0 to 17. GI includes the Sg2 CARE Families Colorectal and Other GI Cancers Including Stomach and Esophagus. Gyn/Onc includes the Sg2 CARE Families Cervical and Other Female Genital Cancer, Including Precancer; Ovarian; and Uterine. Hem/Onc includes the Sg2 CARE Families Non-Hodgkin Lymphoma, Hodgkin Lymphoma, Multiple Myeloma and Leukemia. Gyn/Onc = gynecology/oncology; Hem/Onc = hematology/oncology; CNS = central nervous system; GI = gastrointestinal.
Sources: Impact of Change® v12.0; NIS; Sg2 Analysis, 2012; Sg2 Comparative Database, 2012.

Agenda

Growth in the Volume to Value…to Volume Era

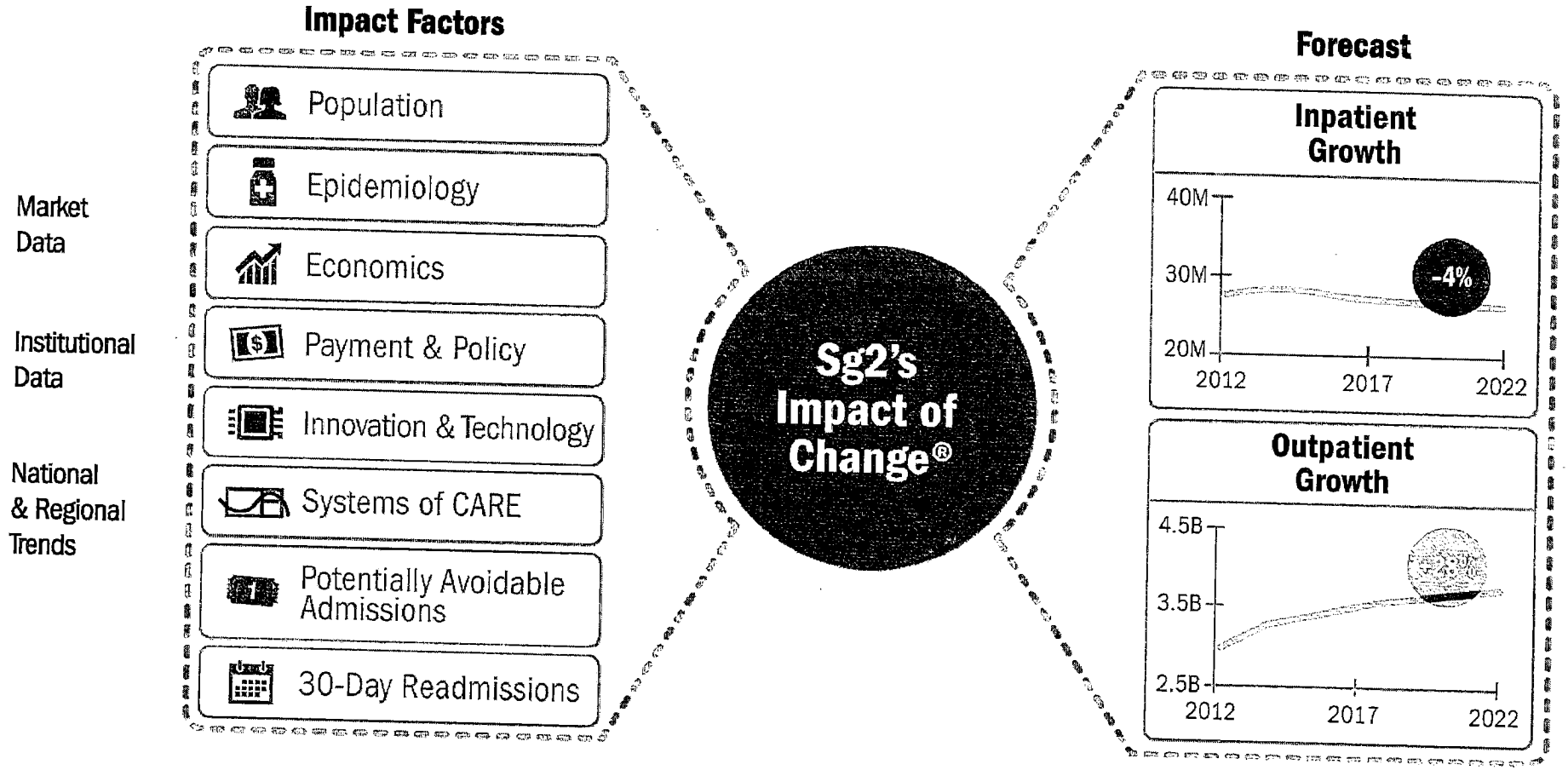
2012 Inpatient and Outpatient Cancer Forecast

Tumor-Specific Growth Opportunities

Building a Coordinated, Aligned Cancer Program

health care intelligence

Impact of Change®: Finding Growth Within Service Lines

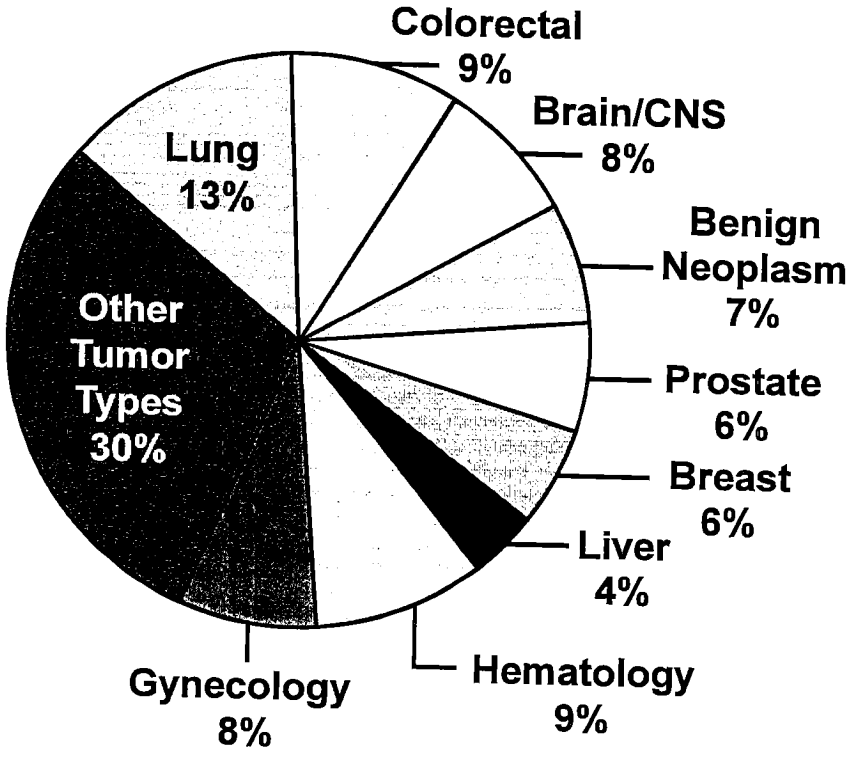


CARE = Clinical Alignment and Resource Effectiveness. M = million; B = billion.
Sources: Impact of Change® v12.0; NIS; PharMetrics; CMS; Sg2 Analysis, 2012.

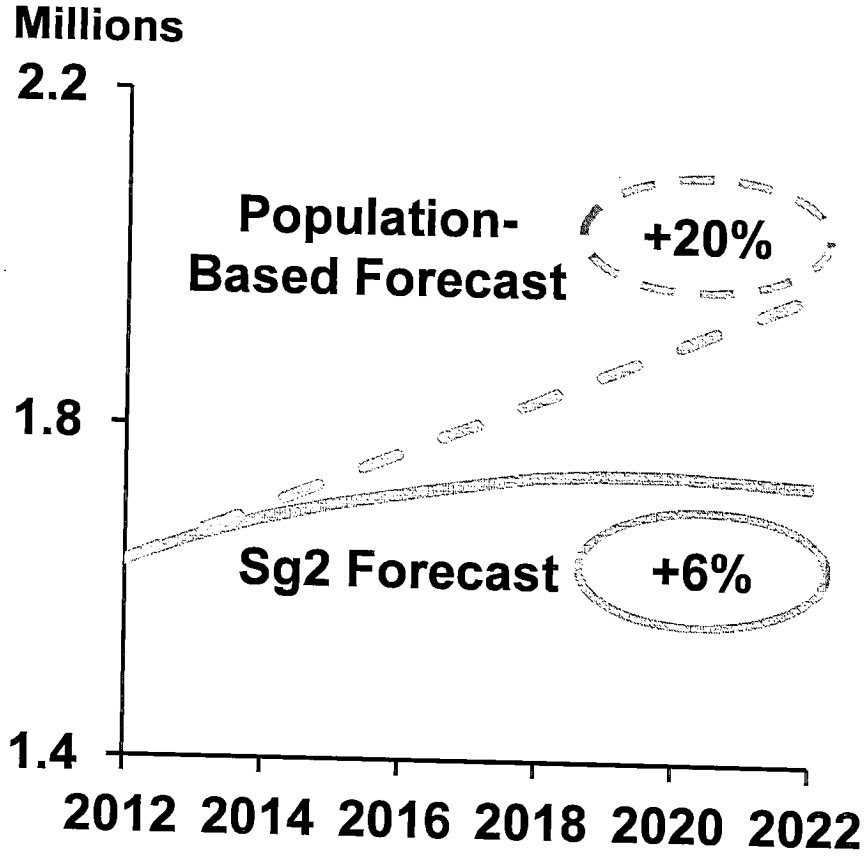
health care intelligence

Moderate IP Growth Across a Wide Variety of Tumors

Inpatient Cancer Discharges US Market, 2012 Total Volume: 1.6 Million



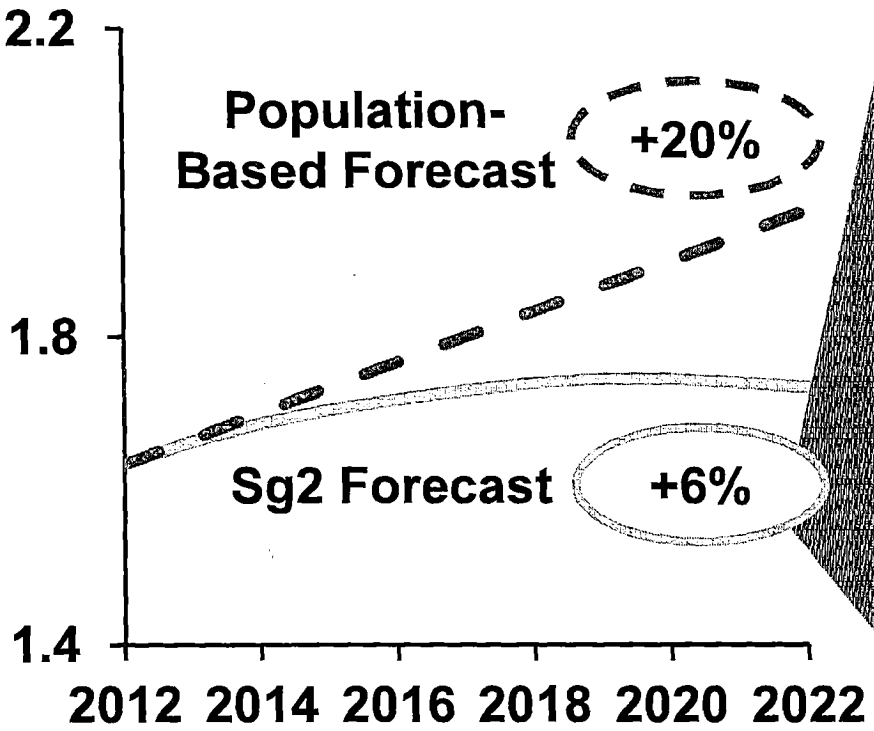
Inpatient Cancer Discharges US Market, 2012–2022



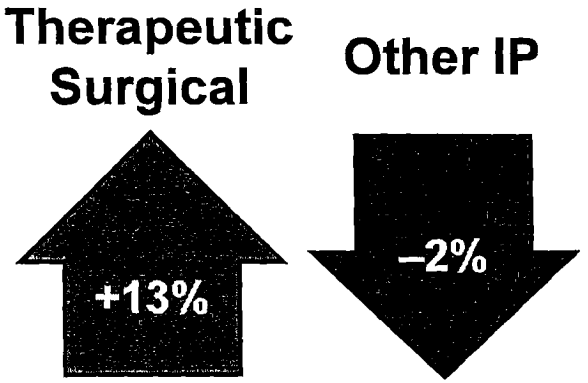
Note: Analysis excludes pediatrics. Hematology includes Sg2 CARE Families Leukemias, Non-Hodgkin Lymphoma, Multiple Myelomas and Hodgkin Lymphoma. Gynecology includes Cervical and Other Female Genital Cancer, Including Precancer; Uterine; and Ovarian. IP = inpatient.
Sources: Impact of Change® v12.0; NIS; Sg2 Analysis, 2012.

Moderate IP Growth Across a Wide Variety of Tumors (Cont'd)

Inpatient Cancer Discharges US Market, 2012–2022



Cancer Discharges, 2012–2022



2012 Data

	Therapeutic Surgical	Other IP
Avg CM	$8,596	$6,185
Avg LOS	5.8 days	6.3 days
30-Day Readmits	9.5%	19.2%

Note: Analysis excludes ages 0–17. Other IP includes Diagnostics, Minor Therapeutic and No Procedure.
Avg = average; CM = contribution margin; LOS = length of stay.
Sources: Impact of Change® v12.0; NIS; Sg2 Analysis, 2012; Sg2 Comparative Database, 2012.

Improved Care Coordination Reduces Demand for Inpatient Services

Medical Home Keeps Patients Out of the Hospital

- Patient navigation and triage line
- Robust patient engagement
- Care pathways
- Electronic medical record

Impact of Medical Home (per Chemotherapy Patient)	
ED Visits	−61%
Hospital Admissions	−44%
Estimated Savings	$8,000

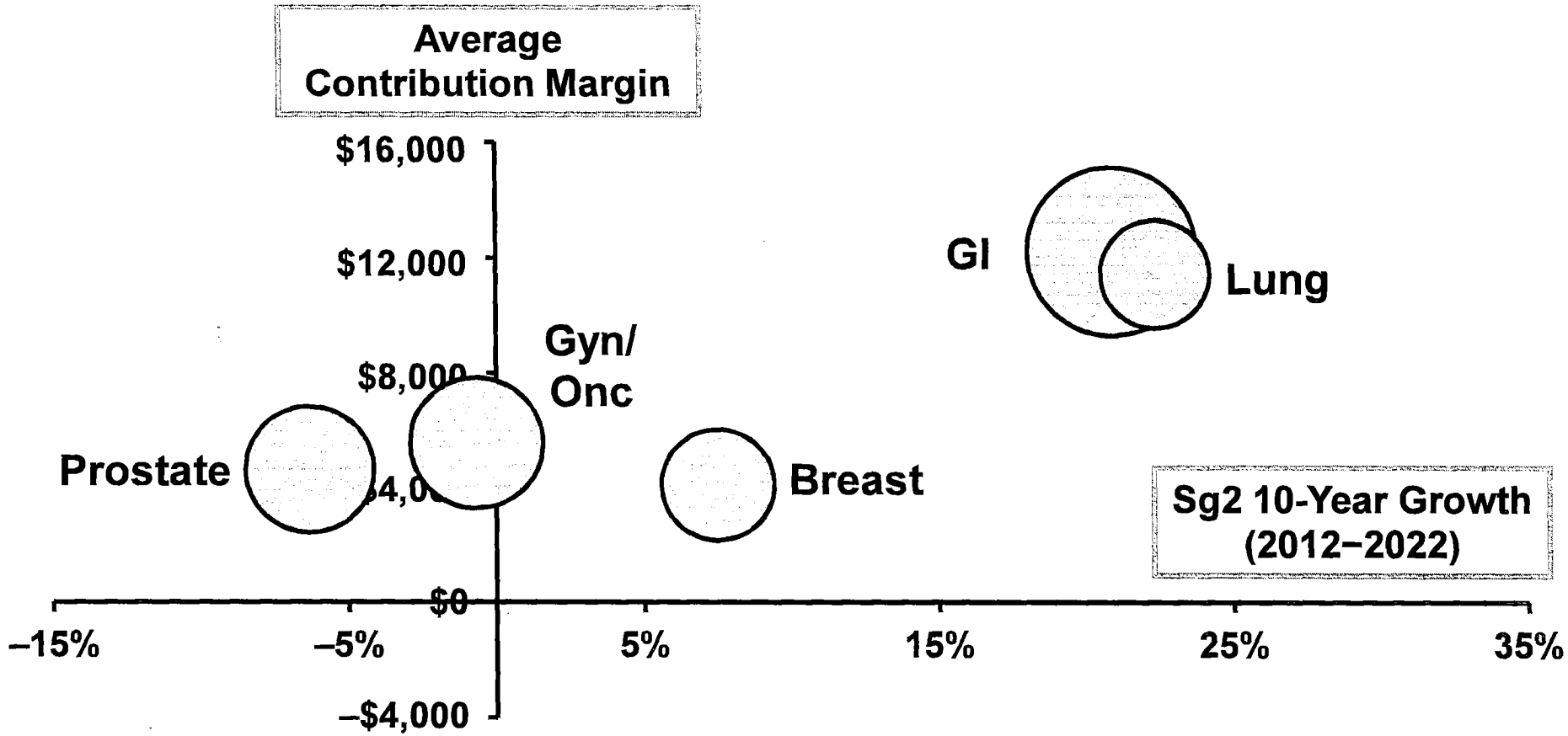
Significant Opportunity to Improve End-of-Life Care

Cancer Patients		Avg	Range	
Dying in Hospital		29%	7%	47%
Final Month	Admitted to Hospital	61%	45%	70%
	Hospital Days	5.1	2.5	7.3
	Enrolled in Hospice	55%	21%	83%

ED = emergency department. Sources: Sprandio J. Oncology patient-centered medical home: transforming the landscape of oncology care. Presented at: 2011 Cancer Center Business Summit, October 2011, Chicago, IL; Goodman DC et al. *Quality of End-of-Life Care for Medicare Beneficiaries: Regional and Hospital-Specific Analyses*. The Dartmouth Institute for Health Policy and Clinical Practice. Published November 2010.

Prioritize Tumor-Specific Surgical Growth Opportunities

Therapeutic Surgical Growth Opportunities for Select Tumor Types

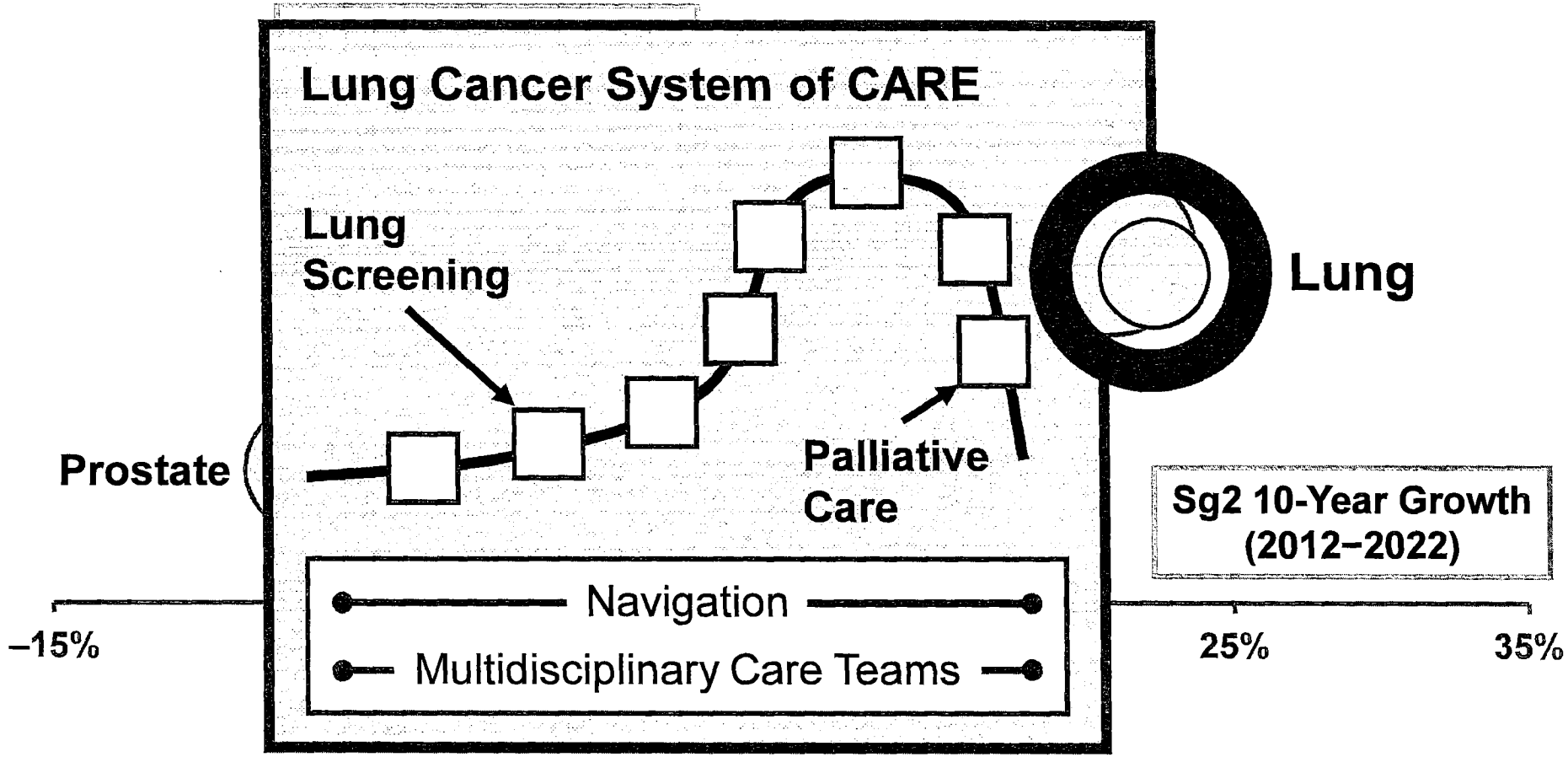


Note: Analysis excludes ages 0–17. Bubble size represents 2012 volumes. GI includes the Sg2 CARE Families Colorectal and Other GI Cancers, Including Stomach and Esophagus. Gyn/Onc includes the Sg2 CARE Families Cervical and Other Female Genital Cancer, Including Precancer; Ovarian; and Uterine.

Sources: Impact of Change® v12.0; NIS; Sg2 Analysis, 2012; Sg2 Comparative Database, 2012.

Capitalizing on Surgical Growth Requires Programmatic Investments

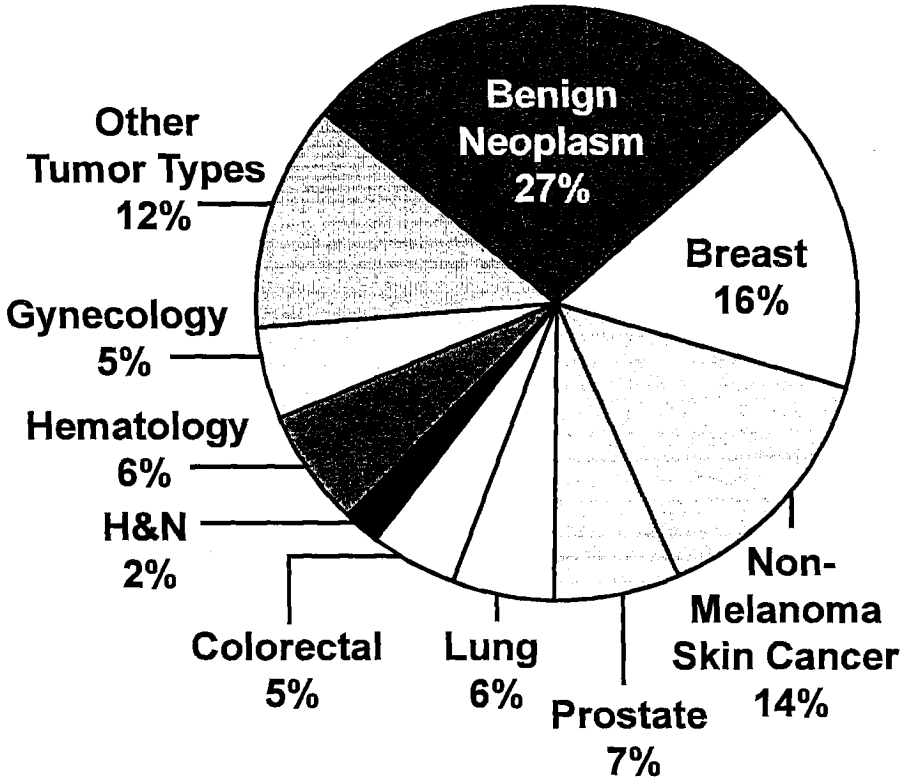
Therapeutic Surgical Growth Opportunities for Select Tumor Types



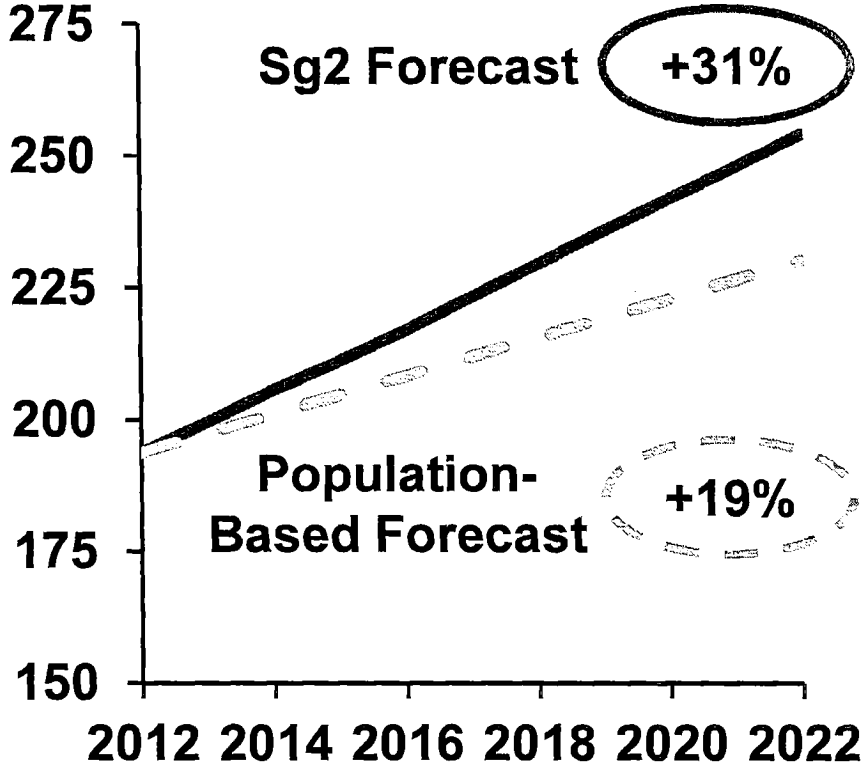
Note: Analysis excludes ages 0–17. Bubble size represents 2012 volumes. GI includes the Sg2 CARE Families Colorectal and Other GI Cancers, Including Stomach and Esophagus. Gyn/Onc includes the Sg2 CARE Families Cervical and Other Female Genital Cancer, Including Precancer; Ovarian; and Uterine.
Sources: Impact of Change® v12.0; NIS; Sg2 Analysis, 2012; Sg2 Comparative Database, 2012.

Growth of OP Cancer Services Will Significantly Outpace IP Growth

Outpatient Cancer Volumes US Market, 2012 Total Volume: 194 Million



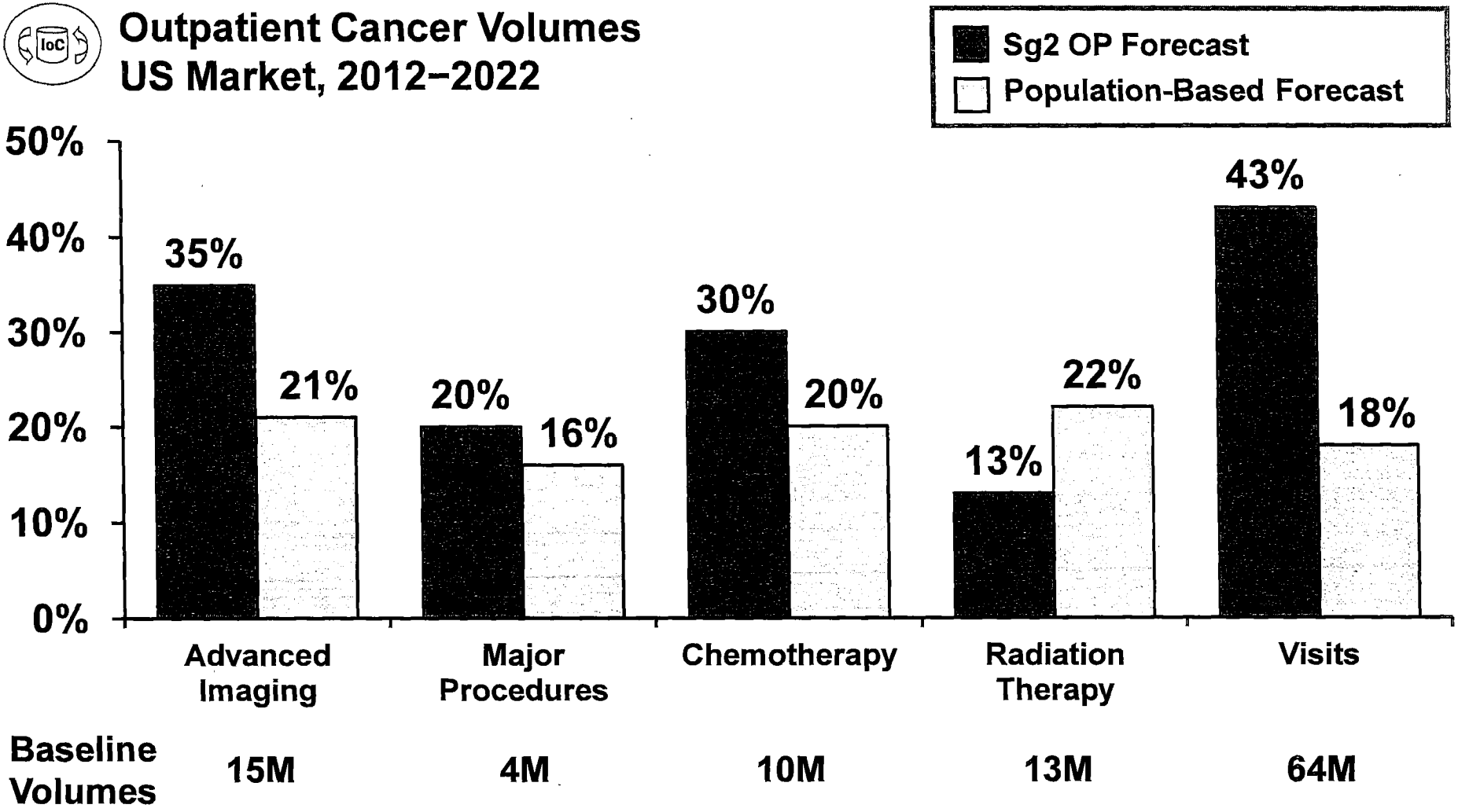
Outpatient Cancer Services US Market, 2012–2022



Note: Analysis excludes pediatrics. Hematology includes the Sg2 CARE Families Leukemias, Non-Hodgkin Lymphoma, Multiple Myeloma and Hodgkin Lymphoma. Gynecology includes Cervical and Other Female Genital Cancer, Including Precancer; Uterine; and Ovarian.
OP = outpatient; H&N = head and neck.
Sources: Impact of Change® v12.0; PharMetrics; CMS; Sg2 Analysis, 2012.

Growth of Outpatient Cancer Services Will Significantly Outpace IP Growth

Outpatient Cancer Volumes US Market, 2012–2022



Note: Forecast excludes ages 0–17. Advanced Imaging includes CT, MRI and PET. CT = computed tomography; MRI = magnetic resonance imaging; PET = positron emission tomography. Source: Impact of Change® v12.0; PharMetrics; CMS; Sg2 Analysis, 2012.

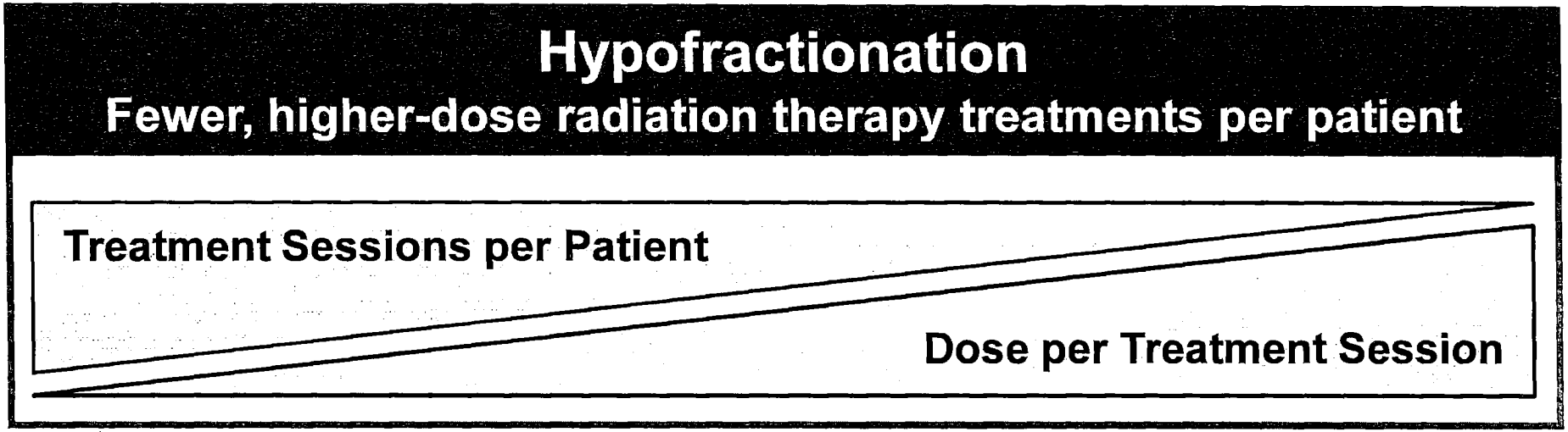
Chemotherapy Growth Will Be Especially Strong in the Hospital Setting

	Chemotherapy Volumes	
	Physician Office	**Hospital**
Current Volumes	7.7M	1.7M
Future Growth	**+**	**+++**

Drivers:

- Reimbursement pressure
  - Low-pay patients to hospital
  - 340B hospital eligibility
- Coordination focus
- Practice acquisition

New Radiation Treatments Favor Fewer Treatments per Patient

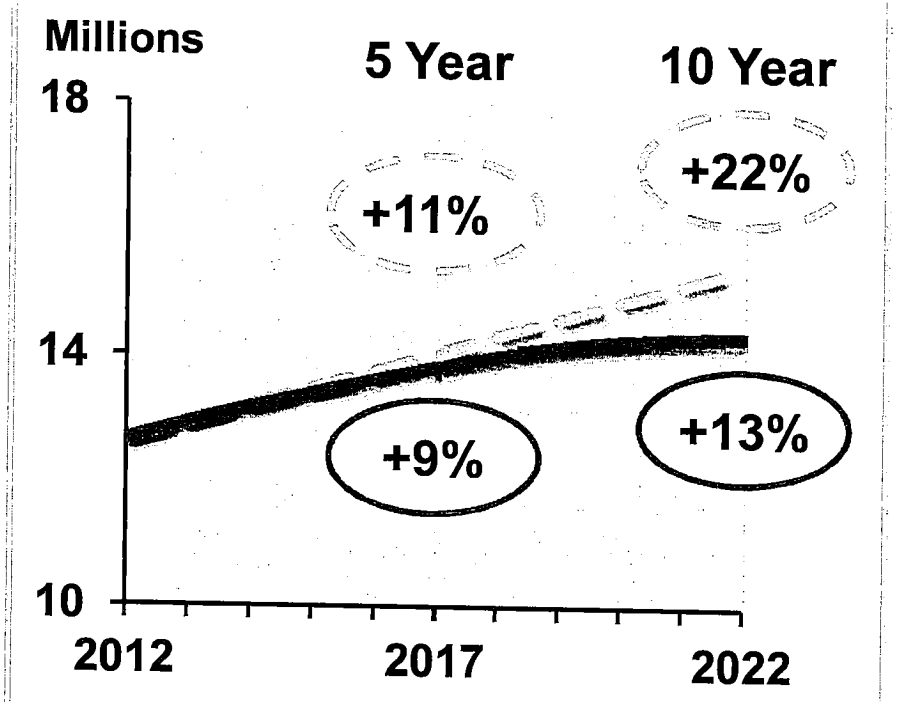


	Conventional Therapy	Hypofractionated Therapy	SRS/SBRT or Intraoperative
Treatment Sessions	25 to 40 fractions	10 to 16 fractions	1 to 5 fractions
Duration	6 weeks	3 weeks	1 week

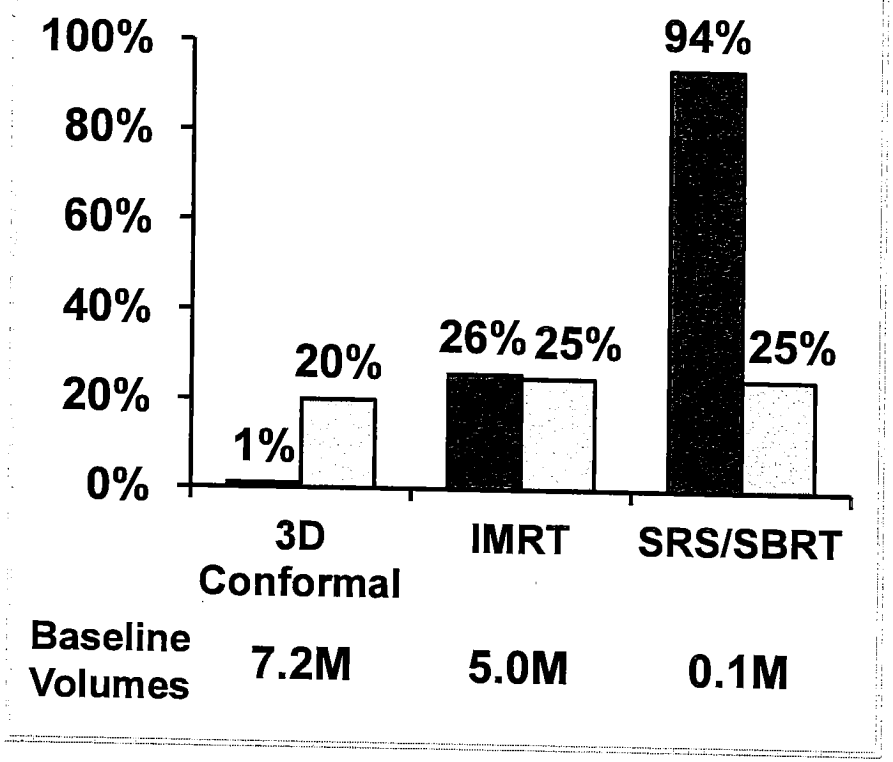
SRS/SBRT= stereotactic radiosurgery/stereotactic body radiation therapy. Source: Sg2 Analysis, 2012.

Hypofractionation Tempers Demand for Key Tumors, Drives SRS/SBRT Growth

Radiation Therapy Forecast*
Sg2 National Forecast, 2012–2022



Treatment Modality Forecast
Sg2 National Forecast, 2012–2022



Sg2 OP Forecast | Population-Based Forecast

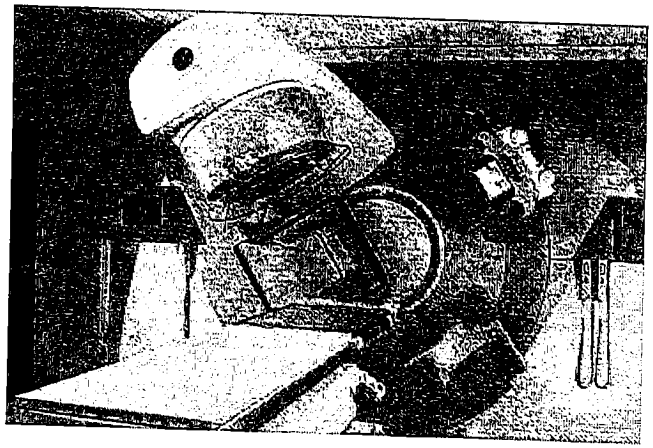
*Includes 3D conformal and IMRT volumes. IMRT = intensity-modulated radiation therapy.
Source: Impact of Change® v12.0; PharMetrics; CMS; Sg2 Analysis, 2012.

Hypofractionation Will Drive Increased Competition for Rad-Onc Patients

Business Impact of Hypofractionation

Sample Program

- 150 breast cancer patients per year
- All treated with 3D conformal therapy
- 50% move from 25- to 16-fraction treatment
- Medicare reimbursement for treatment delivery



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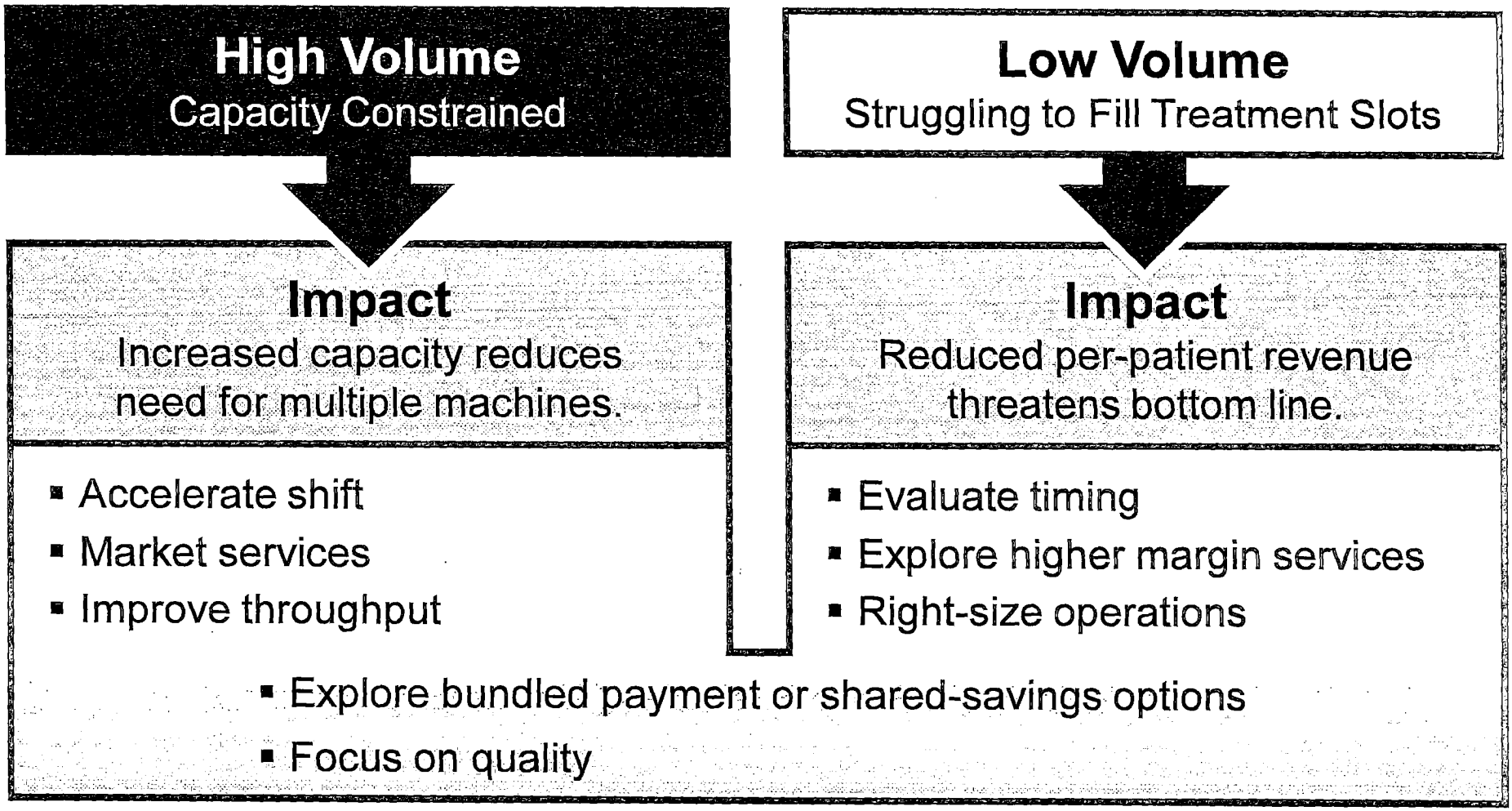
Revenue	Capacity	New Patients Needed
−$114,129	+675 additional treatment slots	+33 breast patients
↓	↑	↑
18% decrease	**18% increase**	**22% increase in patient volume**

Rad-Onc = radiation oncology.
Source: Sg2 Analysis, 2012.

Impact of Hypofractionation Varies by Organization



Agenda

Growth in the Volume to Value…to Volume Era

2012 Inpatient and Outpatient Cancer Forecast

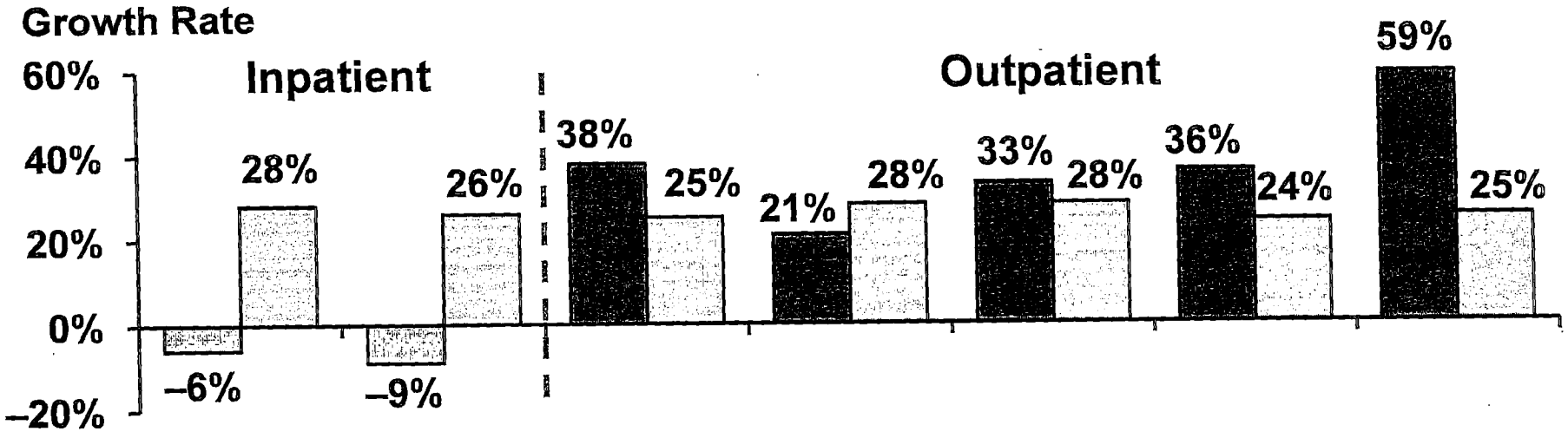
Tumor-Specific Growth Opportunities

Building a Coordinated, Aligned Cancer Program

health care intelligence

Demand Grows for Less-Invasive, Less-Aggressive Prostate Cancer Options

IP and OP Prostate Cancer Service Utilization US Market, 2012–2022



	Therapeutic Surgical	Other IP	Perc Biopsy	IMRT	Brachy	Chemo	Visits
2012 Volumes	94,764	6,455	76,457	2,435,128	35,943	1,071,869	5,418,207

Sg2 IP Forecast | Population-Based Forecast | Sg2 OP Forecast

Note: Therapeutic Surgical includes Sg2 Major Procedures. Other IP includes Sg2 Minor Procedures, Diagnostics and No Procedures. Visits includes E&M visits. Perc = percutaneous; Brachy = brachytherapy; Chemo = chemotherapy; E&M = evaluation and management.
Sources: Impact of Change® v12.0; NIS; PharMetrics; CMS; Sg2 Analysis, 2012.

Multidisciplinary Care Can Affect Patient Decisions, Improve Patient Retention

MDC Impacts Patient Decision Making...

- 3 Boston area academic centers
- Low-risk prostate cancer patients

MDC Impact on Treatment Choice

Treatment	Non-MDC	MDC
Prostatectomy	56%	43%
External Beam Radiation	11%	7%
Brachytherapy	10%	7%
Active Surveillance	22%	43%

...Keeps Patients in The System

- Thomas Jefferson University Hospital
- Weekly GU Cancer Clinic

Patient Satisfaction	
Treatment Option Explained by Doctors	98%
Likelihood of Recommending	98%

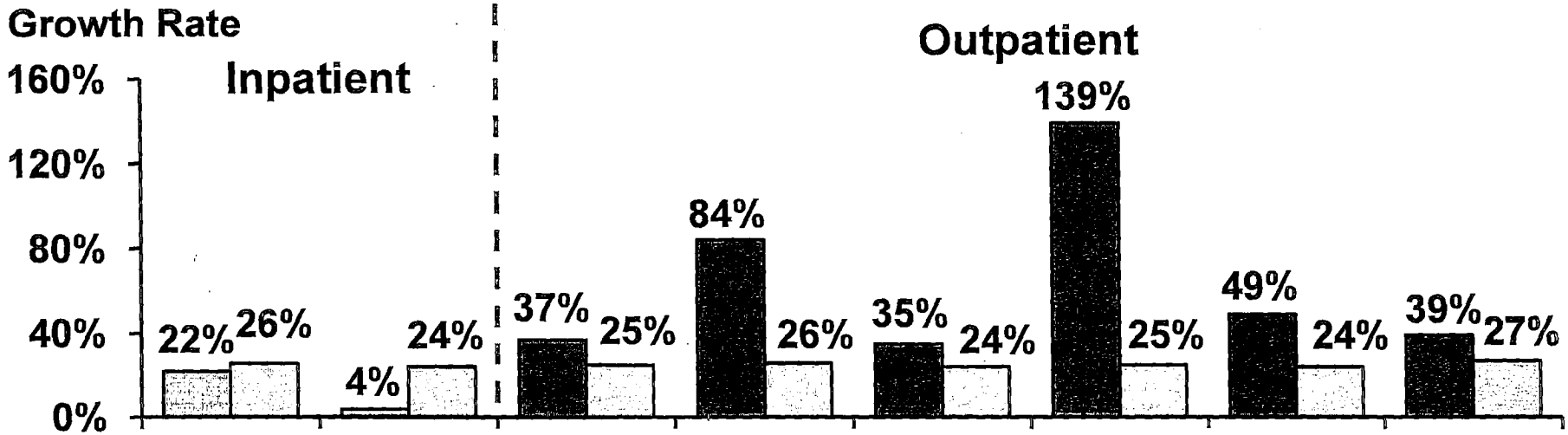
Patients Retained at TJU	
Diagnosed Elsewhere	75%
Diagnosed at TJU	99%

MDC = multidisciplinary clinic; GU = genitourinary.

Sources: Aizer AA, et al. 2012 *J Clin Oncol* Jul 30. [Epub ahead of print]; Gomella LG et al. *J Oncol Pract* 2010;6:e5–e10.

Surgical Admissions for Lung Cancer Will Grow Even as OP Options Emerge

IP and OP Lung Cancer Service Utilization US Market, 2012–2022



	Therapeutic Surgical	Other IP	CT	PET	Chemo	SRS/ SBRT	Visits	Hospice
2012 Volumes	68,832	146,611	1,481,929	442,007	1,202,517	34,022	3,575,118	153,389

Sg2 IP Forecast | Population-Based Forecast | Sg2 OP Forecast

Note: Therapeutic Surgical includes Sg2 Major Procedures. Other IP includes Sg2 Minor Procedures, Diagnostics and No Procedures. Visits includes E&M visits.

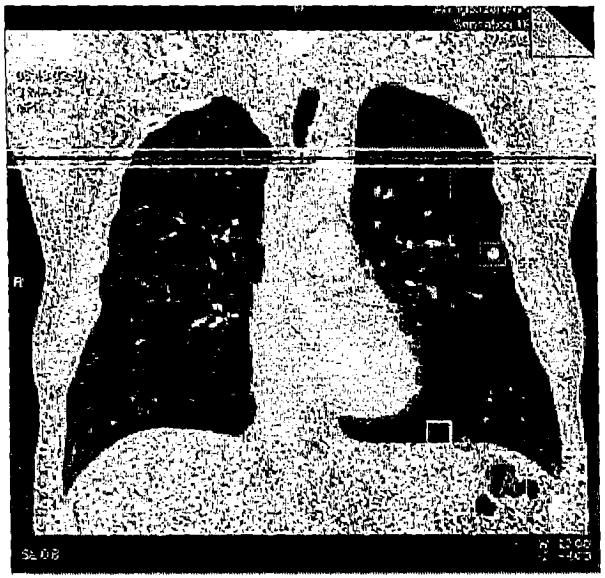
Sources: Impact of Change® v12.0; NIS; PharMetrics; CMS; Sg2 Analysis, 2012.

Sg2 health care intelligence

Lung Cancer Screening Saves Lives, Poised for Growth

National Lung Screening Trial

- 53,000 current and former heavy smokers
- 20% reduction in lung cancer mortality with annual low-dose spiral CT vs x-ray screening
- Recently added as an NCCN Category I recommendation for high-risk patients



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Caveats and Costs

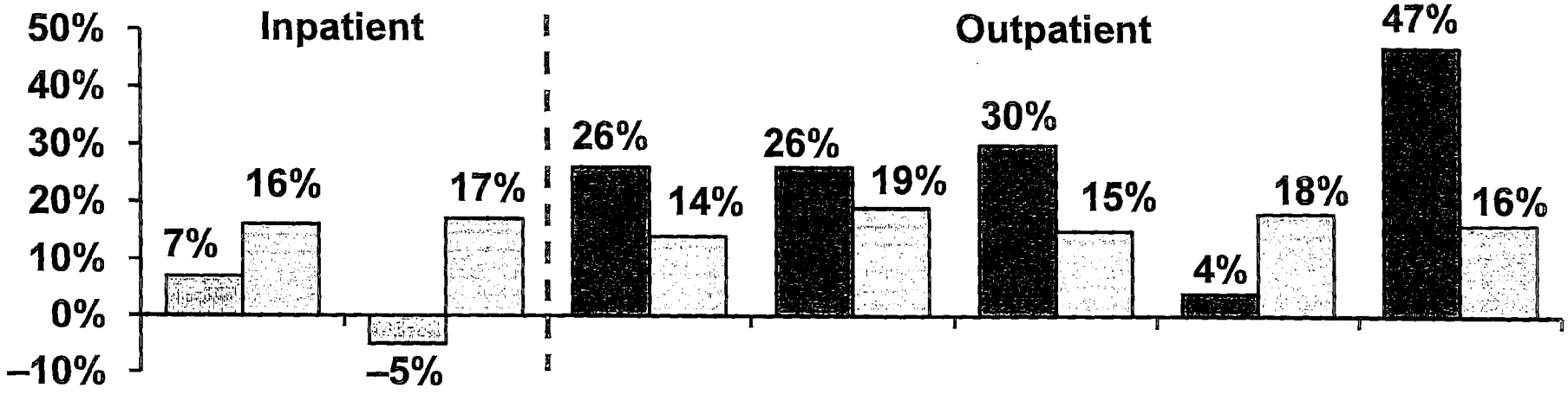
- False-positive rates of 33% by the third screen
- Concerns about total cost of screening program
- Not currently reimbursed by Medicare or most private insurers (WellPoint announced coverage in December.)

Make lung screening part of a **comprehensive lung program** that includes smoking cessation, clear protocols for screening/follow-up and multidisciplinary treatment teams (eg, surgery, radiology, pulmonology, oncology).

NCCN = National Comprehensive Cancer Network. Source: National Cancer Institute. Lung cancer trial results show mortality benefit with low-dose CT [press release]. Published November 4, 2011.

Strong Growth in Outpatient Services, but Radiation Therapy Demand Slows

IP and OP Breast Cancer Service Utilization US Market, 2012–2022



	Therapeutic Surgical	Other IP	Screening Mammo	Lumpectomy	Chemo	Radiation Therapy	Visits
2012 Volumes	73,521	18,308	34,482,400	277,665	2,053,095	3,148,668	11,065,349

Sg2 IP Forecast | Population-Based Forecast | Sg2 OP Forecast

Note: Radiation Therapy includes 3D conformal and IMRT. Therapeutic Surgical includes Sg2 Major Procedures. Other IP includes Sg2 Minor Procedures, Diagnostics and No Procedures. Visits includes E&M visits. Mammo = mammography.
Sources: Impact of Change® v12.0; NIS; PharMetrics; CMS; Sg2 Analysis, 2012.

Intraoperative Radiation Therapy Delivers Treatment in a Single Course

Intraoperative Radiation Therapy

- Radiation delivered directly to tumor/tumor bed during surgery
- Breast cancer TARGIT trial: single 30-minute IORT treatment as effective as 5 to 6 weeks of conventional radiation therapy
- Potential to increase patient convenience, decrease overall costs

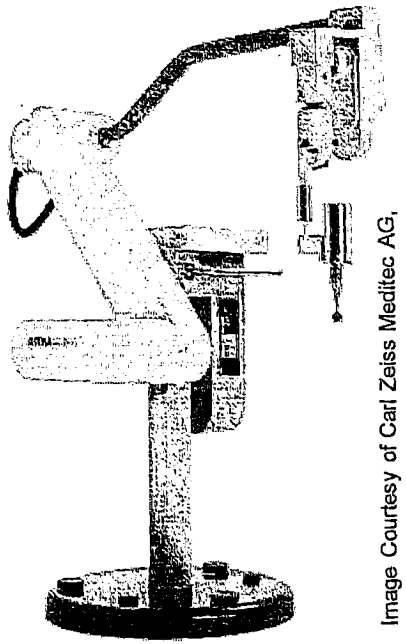


Image Courtesy of Carl Zeiss Meditec AG, Oberkochen, Germany.

New 2012 IORT Codes

- 77424: X-ray IORT treatment delivery
- 77425: Electron IORT treatment delivery
- 77469: IORT treatment management

- New delivery codes have been packaged with surgical procedure.
- IORT treatment delivery not assigned an APC or 2012 reimbursement.
- Commercial payer coverage is mixed.

TARGIT = TARGeted Intraoperative radioTherapy; IORT = intraoperative radiation therapy; APC = ambulatory payment classification. Sources: Vaidya JS et al. *Lancet* 2010;376:91–102; Centers for Medicare & Medicaid Services. *Fed Regist* 2011;76:74122–74584.

Reimbursement Is a Major Headwind to IORT Adoption

2012 Hospital Medicare Reimbursement—Treatment Delivery

Modality	CPT® Code	Medicare Rate/ Fraction	Fractions	Delivery Reimbursement
IORT	77424	$0	1	$0
	77425	$458	1	$458

Proposed for 2013

3D Conformal	77413	$169	25	$4,225
			16	$2,704
IMRT	77418	$458	25	$11,450
			16	$7,328
APBI	77785	$698	10	$6,980

Note: CPT is a registered trademark of the American Medical Association. CPT = Current Procedural Terminology; APBI = accelerated partial breast irradiation. Source: Sg2 Analysis, 2012.

Decision to Adopt IORT Is All About Timing

Accelerators

- Part of larger trend toward hypofractionation
- Outcomes to date equivalent to whole breast irradiation for suitable patients
- Opportunity to improve patient convenience/experience
- Potential program differentiator
- Prepare for new payment models (eg, bundled payment).

Decelerators

- Concerns about long-term outcomes
- Significant reimbursement concerns:
  - Medicare currently not reimbursing
  - Heterogeneous private payer coverage
- Cannibalization of existing volumes that generate margins
- Opportunity to get in later: relatively low start-up costs

Agenda

Growth in the Volume to Value...to Volume Era

2012 Inpatient and Outpatient Cancer Forecast

Tumor-Specific Growth Opportunities

Building a Coordinated, Aligned Cancer Program

SG2
health care intelligence

Strong Alignment Delivers Growth Today and Sets Stage for Accountability

Volume

Grow Market Share

- Capture oncology growth.
- Increase patient satisfaction.
- Reduce patient leakage.
- Improve reimbursement.
- Expand service offerings.

Value

Expand Share of Care™

- Facilitate multidisciplinary care.
- Collaborate on clinical quality initiatives.
- Cooperate on new care delivery and payment models.

There is no one-size-fits-all alignment model:

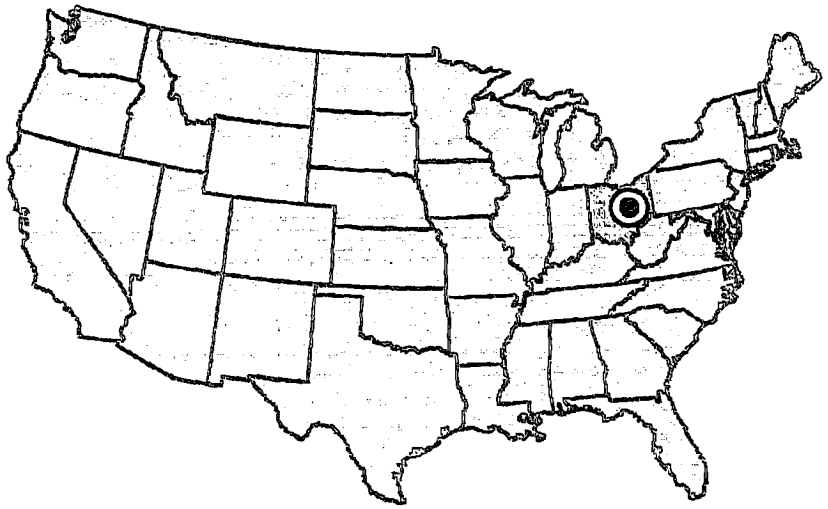
- Employment
- Comanagement agreements
- Professional services agreement
- Joint ventures

Find the Right Partners to Fuel Cancer Program Growth

Genesis HealthCare System, Zanesville, OH

Situation

- Hospital considered physician employment, but local practices were not interested.



Solution

- New medical oncologist hired with shared vision for program

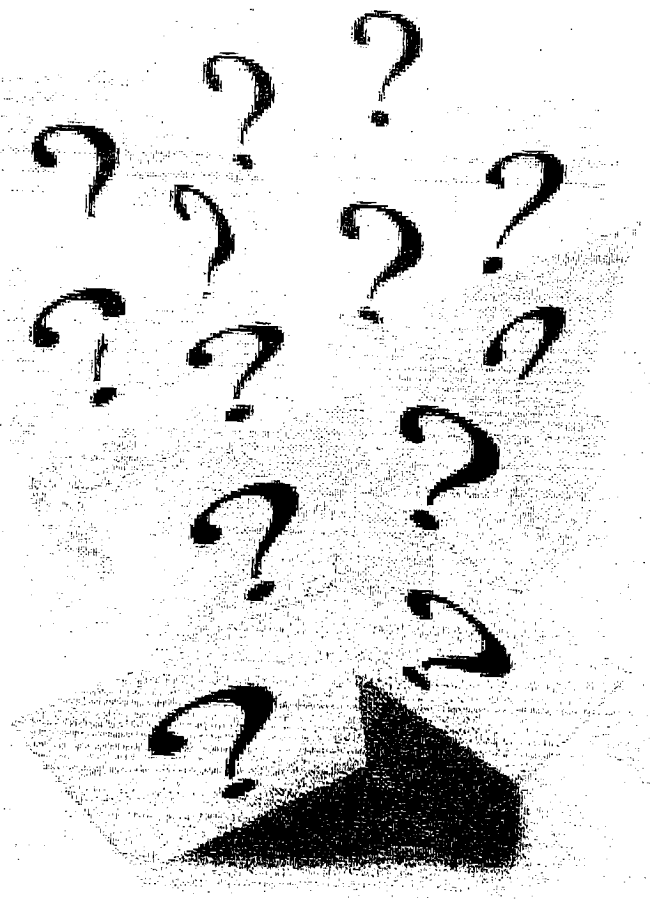
Results

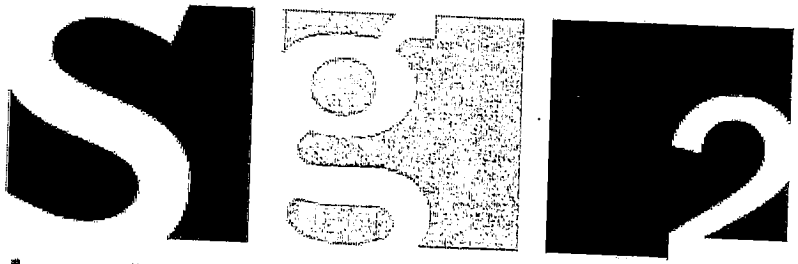
- Program grew to 40 new patients/month in 4 months.
- Second medical oncologist added and planning now to hire a third
- Significant impact on radiation oncology and surgical volumes

Source: Sg2 Interview, April 2012.

Take the Right Steps Now to Attract Volume by Delivering Value in Cancer

- Evaluate your patients' journey through the cancer care continuum. Identify the gaps that impede value.
- Invest in multidisciplinary, tumor-specific programs to capture growth across the System of CARE.
- Enhance outreach to patients through screening and preventive services to improve outcomes and connect them with your system.
- Prepare now for hypofractionation—develop strategic plan to minimize lost revenue and maximize growth.
- Identify mutually beneficial alignment models with the right partners.





health care intelligence

Sg2's analytics-based health care expertise helps hospitals and health systems integrate, prioritize and drive growth and performance across the continuum of care. Over 1,200 organizations around the world rely on Sg2's analytics, intelligence, consulting and educational services.

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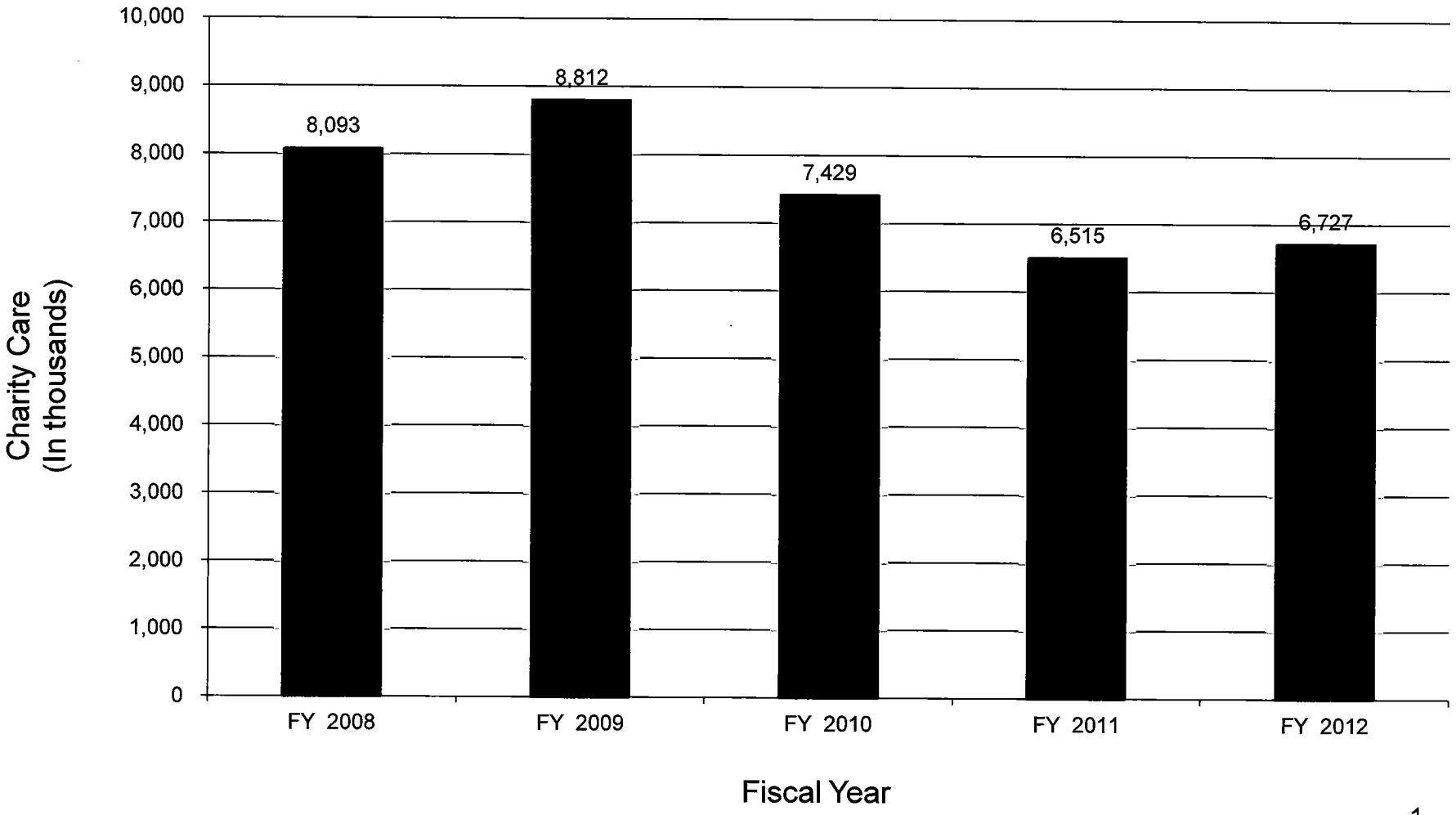
Appendix 53 A

Sibley Memorial Hospital
Trends in Charity Care Actual Figures
FY 2008 - 2012

SIBLEY MEMORIAL HOSPITAL
JOHNS HOPKINS MEDICINE



Appendix 53 B

HOSPITAL POLICY

No.:	03-36-21	**Approved:**	Administration
Effective:	09/15/2009	**Distribution:**	All Departments
Replaces:	Policy dated 05/09/2007	**Reviewed:**	11/09; 7/01; 2/04*revised*

SUBJECT: **Provision of Uncompensated Care and Community Service**

PURPOSE: The purpose of this policy is to outline a program of community service in compliance with the District of Columbia statutory uncompensated care requirements as described in Chapter 44 of the D.C. Municipal Regulations, Title 22.

AREAS AFFECTED: Administration, Finance, Admissions, Emergency Department, Case Coordination, Patient Accounts

RELATED POLICIES:
Finance Policy B-12
03-36-10 Community Assistance Committee
03-36-12 Access to Community Assistance Program

ATTACHMENT: Attachment A - Medical Care for Those Who Cannot Afford to Pay - Sibley Memorial Hospital Community Assistance Program

POLICY:

Sibley Memorial Hospital ("Hospital") will put forth a good faith effort to provide uncompensated services at the annual compliance level required by section 4404 of Chapter 44 of the District of Columbia Municipal Regulations, Title 22 "Provision of Uncompensated Care."

In no event will Sibley deny emergency services to any person on the grounds that the person is unable to pay for services. Sibley may discharge a person who has received emergency services or may transfer the person to another facility when, in the reasonable judgement of appropriate medical personnel, such action is clinically appropriate and in the best interest of the patient and the hospital.

Sibley will provide uncompensated care pursuant to Section 4400.2 of Chapter 44 of the District of Columbia Municipal Regulations, Title 22, "Provision of Uncompensated Care," to eligible persons. The uncompensated care to be provided shall be based upon these rules or contractual obligations between Sibley and the District of Columbia Government, whichever standard provides the higher dollar value.

Uncompensated care is defined in the law governing certificate of needs (DC Code 44-401 in the definitions section). The law defines uncompensated care as the cost of health care services rendered to patients for which the health care facility does not receive payment. The term "uncompensated care" includes bad debt and charity care, but does not include contractual allowances.

Bad debt means an account receivable based on physician and hospital medical services furnished to any patient for which payment is: expected, but is regarded as uncollectible, following reasonable collection efforts; and not the obligation of any federal, state, or local governmental unit. The term bad debt does not include charity care.

Charity care means the physician and hospital medical services provided to persons who are unable to pay for the cost of services, especially those persons who are low-income, uninsured and underinsured, but excluding those services determined to be caused by, or categorized as, bad debt.

For the purpose of this policy, uncompensated care to be provided shall be calculated as follows:

Annual compliance level:

An amount not less than three (3%) percent of Sibley's annual operating expenses, less the amount of reimbursements it receives from Titles XVIII and XIX of the Social Security Act (Medicaid and Medicare), without regard for contractual allowances. In addition, Sibley shall comply with any uncompensated care obligations required pursuant to the Act in a previous CON.

If in any fiscal year Sibley fails to meet its annual uncompensated care obligation, then it shall endeavor to provide uncompensated care in an amount sufficient to make up the deficit in a subsequent year or years, pursuant to a compliance plan approved by the State Health and Planning Development Agency (hereafter SHPDA) but no later than three (3) years after the year in which the deficit occurred.

If Sibley provides uncompensated care during a fiscal year in an amount exceeding its annual compliance level, Sibley may request that the Director apply the excess amount as a credit towards an existing deficit or its annual compliance level for any subsequent fiscal year. To be eligible for a credit, the excess dollar value above the annual compliance level must have been provided pursuant to the requirements of this chapter.

Published Notice of Uncompensated Care Obligation:
Before the beginning of its fiscal year, Sibley will publish a notice of availability of its uncompensated care obligation in a newspaper of general circulation in the District of Columbia. Sibley will also submit a copy of such notice to SHPDA. The Senior Vice President/Chief Financial Officer is responsible for the publishing and submission of this notice. The notice shall include:

a) The dollar value of uncompensated care that Sibley intends to make available during the fiscal year or a statement that Sibley will provide uncompensated care to all persons unable to pay for treatment who request uncompensated care;
b) An explanation of the difference between the amount of uncompensated care Sibley proposes to make available and the annual compliance level for Sibley, if any; and
c) A statement indicating whether Sibley has satisfied all outstanding uncompensated care obligations from previous reporting periods, or a statement indicating that it will, during a specified period, satisfy any outstanding obligations.

Posted Notice of Availability of Uncompensated Care:
A notice announcing the availability of uncompensated care shall also be posted in plain view in the Admissions Department, the Business Office and the Emergency Department. Sibley shall post the following notice:

"Under District of Columbia law, this health care provider must make its services available to all people in the community. This health care provider is not allowed to discriminate against a person because of race, color, religion, national origin, sex, age, marital status, personal appearance, sexual orientation, family responsibilities, matriculation, political affiliation, physical handicap, source of income, or place of residence or business, or because a person is covered by a program such as Medicare or Medicaid."

"This health care provider is also required to provide a reasonable volume of services without charge or at a reduced charge to persons unable to pay. Ask the staff if you are eligible to receive services either without charge or at a reduced charge. If you believe that you have been denied services or consideration for treatment without charge or at a reduced charge without a good reason, contact the Admissions or Business Office of this health care provider, and call the State Health Planning and Development Agency through the Citywide Call Center at 202-727-1000."

"If you want to file a complaint, forms are available from the State Health Planning and Development Agency."

This notice shall also include Sibley's eligibility criteria for uncompensated care. Such notice shall be published in English and Spanish and in any other language which is the usual language of households of ten (10%) percent or more of the populations of the District of Columbia, according to the most recent figures as published by the Bureau of Census. Sibley shall communicate the contents of the posted notice to any person who Sibley has reason to believe cannot read the notice.

Written Notice of Availability of Uncompensated Care:

In any period during a fiscal year in which uncompensated care is available at Sibley, Sibley shall provide written notice of the availability of the services to each person who seeks services from the hospital on behalf of himself or herself or on behalf of another. Sibley will provide this written notice before providing services, except where the emergency nature of services makes prior notice impractical. In emergency situations, Sibley shall provide the written notice to the patient as soon as practical, or to the next of kin. Such notice shall be given not later than when presenting the first bill for services. This individual written notice shall provide the following:

> "Under District of Columbia law, this health care provider must make its services available to all people in the community. This health care provider is not allowed to discriminate against a person because of race, color, religion, national origin, sex, age, marital status, personal appearance, sexual orientation, family responsibilities, matriculation, political affiliation, physical handicap, source of income, or place of residence or business, or because a person is covered by a program such as Medicare or Medicaid."
>
> "This health care provider is also required to provide a reasonable volume of services without charge or at a reduced charge to persons unable to pay. Ask the staff if you are eligible to receive services without charge or at a reduced charge. If you believe that you have been denied services or consideration for treatment without charge or at a reduced charge without a good reason, contact the Admissions or Business Office of this health care provider, and call the State Health Planning and Development Agency through the Citywide Call Center at 202-727-1000. "
>
> "If you want to file a complaint, forms are available from the State Health Planning and Development Agency."

This notice shall also include Sibley's eligibility criteria for uncompensated care, the location of the office where any person seeking uncompensated care may request uncompensated care, and state that Sibley shall make a written determination regarding whether or not the person will receive uncompensated care and the date by, or period within which, the determination will be made. For an example of this form, see Attachment A.

Written Determination of Eligibility for Uncompensated Care:

Sibley will give written notice of its determination of eligibility for uncompensated care in response to each request for uncompensated care to the person requesting care. Notice shall be given in person at the time uncompensated care is requested or by regular mail to the address the person requesting services provided. If the person is not available to receive notice in person and has not provided an address, Sibley may post at its facility, in a conspicuous place, a notice that the person's eligibility status is available in the administrative office of Sibley.

Each written determination of eligibility for uncompensated care shall be made promptly to the applicant. Each determination of eligibility for uncompensated care shall include the following statements:

a) That Sibley will, will with conditions, or will not provide uncompensated care;
b) That there will be no charge for uncompensated care;
c) The date on which the person requested care;
d) The date on which the determination was made;
e) The annual individual or family income, as applicable, and family size of the person who requested uncompensated care;
f) The date on which services were, or will be, provided; and
g) The reason for denial, if applicable.

If an application is submitted prior to the provision of service, Sibley shall make an eligibility determination for uncompensated care within five (5) business days of a complete request for an outpatient service or before discharge for an inpatient service. If the application is submitted after an outpatient service is rendered by the Hospital or after the discharge of an inpatient, Sibley shall make eligibility determination before the completion of the next billing cycle. Normally, the notice of determination will be made within 5 days of the next scheduled meeting of the Community Assistance Committee. Sibley may issue a conditional eligibility determination. Such determination shall state the conditions that the person requesting uncompensated care must satisfy to be eligible.

The Senior Vice President/Chief Financial Officer is responsible for implementing this policy. He/she shall prepare an allocation plan that meets the requirements of the regulations and monitor its implementation. The Senior Vice President/Chief Financial Officer will prepare a report to the SHPDA within 120 days after close of each fiscal year. Documents that support Sibley's determination shall be made available to the public and reported to SHPDA. Such documents shall be maintained by the Senior Vice President/Chief Financial Officer for a period of five (5) years from the date of the last entry for a particular fiscal year. The President and Chief Executive Officer and the Treasurer of the Board shall be kept informed on a periodic basis of Sibley's compliance with the policy.

Definition of the Hospital's Community:

Sibley Memorial Hospital makes its services, including services required under the District of Columbia statutory uncompensated care requirements "to all persons in the community." This community extends to those persons living or working in the hospital's service area or requiring emergency services while otherwise visiting within the service area. Specifically excluded from the Community Assistance Program are those persons requesting elective services who clearly reside outside of the hospital's service area. The Hospital's service area encompasses the District of Columbia and most of Maryland and Virginia, with limited services provided to residents of West Virginia, Delaware and Pennsylvania.

Additional Community Benefits Provided through Community Assistance Program:

As Sibley's financial position allows, the Hospital provides assistance to patients beyond the thresholds established by the District of Columbia's statutory uncompensated care requirements. These benefits are through: 1) Sliding scale discounts to uninsured or underinsured who do not qualify for "uncompensated care" reportable to the District of Columbia, and 2) Collection practices which are more patient friendly and cooperative and less aggressive and oppressive than permissible by law.

1. Sliding Scale Discount

   The following guidelines apply to persons who submit a charity care application but do not meet the guidelines for "Provision of Uncompensated Care" under Chapter 44 of the DC Municipal Regulations, Title 22. These discounts will be periodically evaluated and may be revised upon the approval of the President and CEO. The income thresholds used are those issued by the U.S. Department of Health and Human Services (HHS) as the new "Federal Poverty Guidelines" every year, usually in January or February, and published in the Federal Register. The values are referred to as "Federal Poverty Levels" and are based on income and size of the individual's family unit. Sibley shall update these values each year as soon as practical after they become published, but no later than April 1st. Based on these confirmed income thresholds, the following guidelines shall be used:

Multiple of the Federal Poverty Level	Discount Amount Provided
0 to 2 Times	100% Charity, DC Guidelines
2 to 3 Times	50% Discount
3 to 4 Times	35% Discount
4 to 5 Times	25% Discount
over 5 Times	20% Discount

Note that in the event that the patient balance due is for amounts after payment by insurance, the Hospital may reduce the self pay discount by the amount of the contractual insurance discount which has already been provided. If the primary insurer (e.g.: Medicare) has already required a discount of over 50%, then additional discounts may not be feasible.

2. Collection Practices

For those patients who apply for assistance through the Community Assistance Program (hereinafter "CAP Patients"), the Hospital will also procedurally assist the patient by applying favorable collection practices to their situation. Some of the practices are described below.

a. Sibley will communicate the hospital's level of assistance with hospital-based physicians involved with the patient's care in hopes that those physicians may similarly participate in the assistance, as feasible.
b. The Hospital will notify any Collection Agency to which the Hospital has referred accounts and ensure appropriate discounts are applied.
c. When a CAP patient has been approved under the hospital's charity care policy for a partial discount, the hospital will work with the patient or responsible party to establish a reasonable payment plan, which takes into account available income and assets, the amount of the discounted bill(s), and any prior payments. The hospital will advise the CAP patient of his or her responsibilities.
d. In lieu of charging interest, the Hospital pay offer prompt pay discounts for patients to settle account expeditiously (e.g.: financing balance with a credit card).
e. The hospital will not pursue legal action for non-payment of bills against CAP patients who have clearly demonstrated that they have neither sufficient income nor assets to meet their financial obligations.
f. Legal actions, including judgment and liens against wages or assets may be taken by the hospital to enforce the terms of a payment plan when there is evidence that the Cap patient or responsible party has sufficient resources to pay the bill, but appears to be unwilling.
g. The Hospital will not place a lien on a CAP patient's primary residence if this is the patient's sole real asset unless the value of the property indicates the ability to assume significant financial obligations. The hospital will not execute a lien by forcing the sale or foreclosure of the CAP patient's primary residence to pay for an outstanding obligation to the hospital.
h. The hospital will not use bodily attachment to require the CAP patient or responsible party to appear in court.

i. The hospital will not routinely report balance due from CAP patients to the any credit bureau nor allow Collection Agencies working for the hospital to report such debts. However, these debts may be reported to a credit bureau only upon the account-specific signed approval of the Director of Patient Financial Services if in his/her judgment the CAP patient is uncooperative with resolving that debt.

j. The Hospital will not advance the collection process, including referral to Collection Agency, once the patient has indicated a desire to apply for consideration under the Community Assistance Program. However, the patient must submit a complete application and submit additional information requested within 30 days of request, and must subsequently respond to attempts to make payment arrangements. Once a determination has been made and a balance is determined to be due, the normal collection process (except as modified by this section) shall apply.

k. If a patient receiving a sliding scale discount appeals the decision indicating that he/she is still unable to pay, the Committee may consider capping the patient's annual liability at 25 percent of his/her annual income.

KEY: ***Bold, italicized*** wording = new or changed wording
= omitted word(s)

APPROVALS:

_____
Senior Vice President and CFO

_____
President and CEO

ATTACHMENT A

Medical Care for Those Who Cannot Afford to Pay
Sibley Memorial Hospital Community Assistance Program

Under District law, Sibley Memorial Hospital has an obligation to make its services available to all people in the community. Sibley Memorial Hospital is not allowed to discriminate against a patient or applicant for services because of race, color, religion, national origin, sex, age, marital status, personal appearance, sexual orientation, family responsibilities, matriculation, political affiliation, physical handicap, source of income, or place of residence or business,.or because a patient or applicant for services is covered by a program such as Medicare or Medicaid. Sibley Memorial Hospital is also obligated to provide a reasonable volume of services without charge or at a reduced charge to persons unable to pay.

If you would like to apply for financial assistance concerning your hospital bill, please contact the Financial Counselors located in the Admissions Department at 202-537-4160 or 202-537-4161. You will be required to fill out an application that includes information about your family size, family income, family expenses and other personal data. This information will be reviewed and a decision will be made by a committee. Hospital criteria will use the Federal Poverty Guidelines in determining your eligibility for financial assistance. A written determination of your eligibility will be sent to you within 30 days after the hospital receives a complete application with all requested documentation.

If you believe that you have been improperly denied services, contact the Financial Counselors Office of Sibley Memorial Hospital at 202-537-4160 or 202-537-4161, or call the District Health Planning and Development Agency (SHPDA) at 202-442-5875 (or such other telephone number as the SHPDA may designate by notifying the health care provider in writing).