

Acquire Linear Accelerator

Project #6140 HS

Mercy Hospital South St. Louis, MO

September 2024



NEW OR ADDITIONAL EQUIPMENT APPLICATION

Applicant's Completeness Checklist and Table of Contents

Project Name:	Project No:
Project Description:	

Done Page N/A

Description

Divider I. Application Summary:

- 1. Applicant Identification and Certification (Form MO 580-1861)
- 2. Representative Registration (From MO 580-1869)
- 3. Proposed Project Budget (Form MO 580-1863) and detail sheet with documentation of costs.

Divider II. Proposal Description:

- 1. Provide a complete detailed project description and include equipment bid quotes.
- 2. Provide a timeline of events for the project, from CON issuance through project completion.
- 3. Provide a legible city or county map showing the exact location of the project.
- 4. Define the community to be served and provide the geographic service area for the equipment.
- 5. Provide other statistics to document the size and validity of any user-defined geographic service area.
- 6. Identify specific community problems or unmet needs the proposal would address.
- 7. Provide the historical utilization for each of the past three years and utilization projections through the first three (3) **FULL** years of operation of the new equipment.
- 8. Provide the methods and assumptions used to project utilization.
- 9. Document that consumer needs and preferences have been included in planning this project and describe how consumers had an opportunity to provide input.
- 10. Provide copies of any petitions, letters of support or opposition received.
- 11. Document that providers of similar health services in the proposed service area have been notified of the application by a public notice in the local newspaper.
- 12. Document that providers of all affected facilities in the proposed service area were addressed letters regarding the application.

Divider III. Service Specific Criteria and Standards:

- 1. For new units, address the minimum annual utilization standard for the proposed geographic service area.
- 2. For any new unit where specific utilization standards are not listed, provide documentation to justify the new unit.
- 3. For additional units, document compliance with the optimal utilization standard, and if not achieved, provide documentation to justify the additional unit.
- 4. For evolving technology address the following:
 - Medical effects as described and documented in published scientific literature;
 - The degree to which the objectives of the technology have been met in practice;
 - Any side effects, contraindications or environmental exposures;
 - The relationships, if any, to existing preventive, diagnostic, therapeutic or management technologies and the effects on the existing technologies;
 - Food and Drug Administration approval;
 - The need methodology used by this proposal in order to assess efficacy and cost impact of the proposal;
 - The degree of partnership, if any, with other institutions for joint use and financing.

Divider IV. Financial Feasibility Review Criteria and Standards:

- 1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.
- Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) FULL
 years beyond project completion.
- 3. Document how patient charges are derived.
- 4. Document responsiveness to the needs of the medically indigent.

	Mercy Hospital South Certificate of Need Application
Divider I	
Application Summary	y

DIVIDER I – Application Summary

1. Applicant Identification and Certification (Form MO 580-1861).

The Application Identification and Certification form is included in Divider I - Attachments.

2. Representative Registration (Form MO 580-1869).

Representative Registration form is included in Divider I – Attachments.

3. Proposed Project Budget (Form MO 580-1863) and detail sheet with documentation of costs.

The Proposed Project Budget Form is included in Divider I – Attachments.

	Mercy Hospital South Certificate of Need Application
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Application Summar	\mathbf{y}



APPLICANT IDENTIFICATION AND CERTIFICATION

The information provided must match the Letter of Intent for this project, without exception.							
1. Project Location (Attach additional	al pages as neces	sary to identify multi	ple project sites.)			
Title of Proposed Project Acquire Linear Accelerator Project Number 6140 HS							
Project Address (Street/City/State/Zip Code)				County			
10010 Kennerly Road St. Louis, MO 631	28			St. Louis Cou	s County		
2. Applicant Identification (Inf	ormation must ag	ree with previously s	ubmitted Letter	of Intent.)			
List All Owner(s): (List corporate entity	ı.)	Address (Street/			Т	Telephone Number	
Mercy Health East Communities		615 S. New Ballas	Road, St. Louis	s, MO 63141		314-251-1952	
(List entity to be List All Operator(s): licensed or certif	ied.) Addı	ress (Street/City/S	state/Zip Code	e)	Telepho	one Number	
Mercy Hospital South		10010 Kennerly Ro				314-525-000	
3. Ownership (Check applicable category,)						
☑ Nonprofit Corporation [Individua	al 🗆	City		District	:	
☐ Partnership [Corporat	ion 🗌	County		Other_		
4. Certification							
In submitting this project application	n, the applica	ant understand	s that:				
 (A) The review will be made as to the community need for the proposed beds or equipment in this application; (B) In determining community need, the Missouri Health Facilities Review Committee (Committee) will consider all similar beds or equipment within the service area; (C) The issuance of a Certificate of Need (CON) by the Committee depends on conformance with its Rules and CON statute; (D) A CON shall be subject to forfeiture for failure to incur an expenditure on any approved project six (6) months after the date of issuance, unless obligated or extended by the Committee for an additional six (6) months: (E) Notification will be provided to the CON Program staff if and when the project is abandoned; and (F) A CON, if issued, may not be transferred, relocated, or modified except with the consent of the Committee. 							
We certify the information and date i representative's signature below:	n this applic	ation as accura	te to the be	st of our know	ledge an	d belief by our	
5. Authorized Contact Person (Attach a Contact Person Correction Form if different from the Letter of Intent.)							
Name of Contact Person Tyler Sturgeon			Ch	e lief Financial Office	r		
Telephone Number 314-525-1930	Fax Number			nail Address er.sturgeon@merc	y.net		
Signature of Contact Person	<u></u>		Da	te of Signature	8	730/24	



REPRESENTATIVE REGISTRATION

(A registration form must be completed for each project presented.)				
ect Name Number Cquire Linear Accelerator 6140 HS		10		
Acquire Linear Accelerator	01401	10		
(Please type or print legibly.)				
Name of Representative	Title			
Tyler Sturgeon	Chief F	inancial Officer		
Firm/Corporation/Association of Representative (may be different from below, e.g., law firm, consultant, other)		Telephone Number		
Mercy		314-525-1930		
Address (Street/City/State/Zip Code)				
10010 Kennerly Road, St. Louis, MO 63128				
Who's interests are being represented? (If more than one, submit a separate Representative Registration Form for each separate Registration F	ach.)			
Name of Individual/Agency/Corporation/Organization being Represented		Telephone Number		
Mercy Health East Communities-Mercy Hospital South		314-525-1000		
Address (Street/City/State/Zip Code)				
10010 Kennerly Road St. Louis, MO 63128				
Check one. Do you: Relation	nship t	to Project:		
☑ Support	None	e		
Oppose	☑ Emp	ployee		
☐ Neutral	Lega	l Counsel		
	Cons	sultant		
	Lobb	pyist		
Other Information:	Othe	er (explain):		
I attest that to the best of my belief and knowledge the testimony and information presented by me is truthful, represents factual information, and is in compliance with §197.326.1 RSMo which says: Any person who is paid either as part of his normal employment or as a lobbyist to support or oppose any project before the health facilities review committee shall register as a lobbyist pursuant to chapter 105 RSMo, and shall also register with the staff of the health facilities review committee for every project in which such person has an interest and indicate whether such person supports or opposes the named project. The registration shall also include the names and addresses of any person, firm, corporation or association that the person registering represents in relation to the named project. Any person violating the provisions of this subsection shall be subject to the penalties specified in §105.478, RSMo.				
Original Signature		8/30/24		

MO 580-1869 (11/01)



PROPOSED PROJECT BUDGET

Descri	<u>ption</u>	<u>Dollars</u>
COSTS	3: *	(Fill in every line, even if the amount is "\$0".)
1.	New Construction Costs ***	
2.	Renovation Costs ***	
3.	Subtotal Construction Costs (#1 plus #2)	
4.	Architectural/Engineering Fees	
5.	Other Equipment (not in construction contract)	
6.	Major Medical Equipment	
7.	Land Acquisition Costs ***	
8.	Consultants' Fees/Legal Fees ***	
9.	Interest During Construction (net of interest ear	ned) ***
10.	Other Costs ***	
11.	Subtotal Non-Construction Costs (sum of #4 th	hrough #10
12.	Total Project Development Costs (#3 plus #11	**
FINAN	CING:	
13.	Unrestricted Funds	
14.	Bonds	
15.	Loans	
16.	Other Methods (specify)	
17.	Total Project Financing (sum of #13 through #	16) **
18.	New Construction Total Square Footage	
19.	New Construction Costs Per Square Foot *****	
20.	Renovated Space Total Square Footage	
21.	Renovated Space Costs Per Square Foot ******	

- * Attach additional page(s) detailing how each line item was determined, including all methods and assumptions used. Provide documentation of all major costs.
- ** These amounts should be the same.
- *** Capitalizable items to be recognized as capital expenditures after project completion.
- **** Include as Other Costs the following: other costs of financing; the value of existing lands, buildings and equipment not previously used for health care services, such as a renovated house converted to residential care, determined by original cost, fair market value, or appraised value; or the fair market value of any leased equipment or building, or the cost of beds to be purchased.
- ***** Divide new construction costs by total new construction square footage.
- ***** Divide renovation costs by total renovation square footage.

	Mercy Hospital South Certificate of Need Application
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Proposal Description	1

DIVIDER II – Proposal Description

1. Provide a complete detailed project description and include equipment bid quotes.

Mercy is requesting CON approval to acquire an additional linear accelerator at Mercy Hospital South. This cutting-edge technology will significantly enhance our capabilities in delivering precise, minimally invasive treatments for various conditions.

The Accuray CyberKnife is the first and only fully robotic radiotherapy device, offering unparalleled precision in targeting tumors and other abnormalities. This system is versatile, with primary applications in treating cancers of the prostate, lung, brain, spine, liver, pancreas, and kidney. Utilization of robotic radiotherapy is rapidly becoming the standard of care, and Mercy Hospital South is committed to staying at the forefront of this technological advancement.

The benefits of the CyberKnife System include:

- Non-invasive treatment: No incisions are required, reducing the risk of infection and complications.
- High precision: The system delivers targeted radiation with sub-millimeter accuracy, sparing healthy tissues.
- Shorter treatment times: Patients typically require fewer sessions compared to traditional radiation therapy.
- Minimal recovery time: Most patients can return to their normal activities immediately after treatment.



1. Provide a complete detailed project description and include equipment bid quotes. (continued)

The proposed project budget includes:

Equipment:	\$ 3,375,000
-Accuray CyberKnife S7 FIM System	
-Precision Treatment Planning System Workstation	
-Patient Positioning System (Flat Top)	
Total Project Cost	\$ 3,375,000

Quotation from Accuray is included in Divider I attachments. The equipment quote is valid.

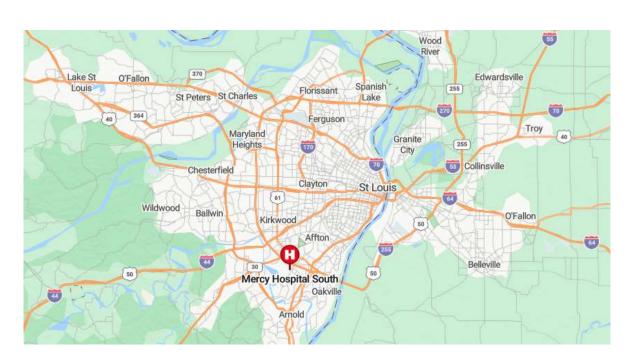
2. Provide a timeline of events for the project, from CON issuance through project completion.

Project timeline assumes CON issuance November 2024

Equipment Arrival: March 2025Training & Testing: April 2025

• Go-Live: May 2025

3. Provide a legible city or county map showing the exact location of the project.



4. Define the community to be served and provide the geographic service area for the equipment.

The David M. Sindelar Cancer Center at Mercy Hospital South serves a diverse community in the St. Louis region, focusing on providing comprehensive cancer care to patients from various backgrounds. The center is dedicated to addressing the needs of cancer patients by offering state-of-the-art treatments and personalized care. It serves individuals diagnosed with various types of cancer, including prostate, lung, brain, spine, liver, pancreas, and kidney cancers. Additionally, the center provides support and resources to families and caregivers and collaborates with local healthcare providers to ensure coordinated and effective treatment plans. The Sindelar Cancer Center aims to provide cutting-edge cancer care and improve patient outcomes across a broad geographic region.

Mercy Hospital serves patients in its primary service area which includes St. Louis City, St. Louis County, Jefferson, Franklin, St. Francois and Ste. Genevieve counties.

5. Provide other statistics to document the size and validity of any user-defined geographic service area.

Mercy Hospital South serves patients from a large geographic area. According to the Missouri Department of Health and Senior Services the 2025 estimated population projections for the six counties in Mercy South's primary service area is 1.6 million. The population projections are documented in the table below:

County	2025 Total County Population	2025 65+ Population
Franklin	106,645	21,530
Jefferson	228,389	40,939
St. François	68,252	12,902
St. Louis City	277,256	45,114
St. Louis County	990,180	202,698
Ste. Genevieve	17,783	3,989
Total	1,595,846	327,172

Source: MO Department of Health & Senior Services

In 2023, the David M. Sindelar Cancer Center at Mercy Hospital South diagnosed 2,072 cancer cases. According to the American Cancer Society, the estimated number of new cancer cases in Missouri for 2023 was approximately 37,000, indicating that the Sindelar Cancer Center handled a significant portion of the state's cancer cases. The St. Louis region is home to several major healthcare facilities, but the Sindelar Cancer Center focuses on advanced treatments, which makes the Accuray CyberKnife, a critical resource for patients seeking specialized cancer care. In 2023, the most diagnosed types of cancer at the David M. Sindelar Cancer Center included prostate, lung, and colon cancers for men, and breast, lung, and colon cancers for women. These types of cancer accounted for a significant portion of the total cancer cases diagnosed at the center, reflecting broader national trends.

6. Identify specific community problems or unmet needs the proposal would address.

The CyberKnife system is a groundbreaking advancement in cancer treatment, addressing several critical community needs. Traditional cancer treatments often involve invasive surgeries, lengthy recovery periods, and significant side effects. In contrast, the CyberKnife offers a non-invasive alternative, delivering precise, targeted radiation therapy that minimizes recovery time and reduces side effects, significantly improving the patient experience.

With the rising incidence of cancer in the region, including over 2,072 cases treated in 2023 alone, there is an urgent need for advanced treatment options. The CyberKnife can treat a wide range of cancers, including those of the prostate, lung, brain, spine, liver, pancreas, and kidneys. This versatility makes it an invaluable tool in addressing the growing demand for effective cancer treatments.

Patients and physicians are increasingly seeking non-invasive treatment options that reduce the risk of complications and enhance the quality of life. The CyberKnife meets this demand by offering high precision and real-time image guidance, which allows for shorter treatment times and enables patients to return to their normal activities more quickly.

Mercy Hospital South is a key healthcare provider in the St. Louis region. The CyberKnife's ability to deliver precise, targeted radiation makes it essential for treating complex and hard-to-reach tumors, thereby improving patient outcomes.

Looking ahead, the projected population growth in the service area underscores the need for advanced medical technologies to meet future healthcare demands. The CyberKnife ensures that Mercy Hospital South remains at the forefront of medical innovation, providing the community with access to the best possible care. By addressing these unmet needs, the CyberKnife significantly enhances the quality of care provided, offering cutting-edge treatment options, and improving patient outcomes across the hospital's extensive service area.

7. Provide the historical utilization for each of the past three years and utilization projections through the first three (3) FULL years of operation of the new equipment.

Historical Utilization (2 units)			
FY2022	20,579		
FY2023	20,775		
FY2024	21,821		
Projected Utilization (3 units)			
Year 1	24,615		
Year 2	25,347		
Year 3	26,121		

Mercy's fiscal year runs from July 1-June 30 each year.

8. Provide the methods and assumptions used to project utilization.

Projected utilization for the CyberKnife is based on historical data and trends in cancer treatment demand. Utilization projections are grounded in the center's historical data on patient volumes and treatment types. Over the past five years, there has been a steady increase in the number of patients receiving advanced radiation therapies, including stereotactic body radiation therapy and stereotactic radiosurgery.

The CyberKnife offers precise, non-invasive treatment options for various cancers, which has led to increased patient preference for this technology. The center anticipates continued growth in CyberKnife utilization due to ongoing advancements and positive patient outcomes.

The St. Louis region has a growing population, particularly among individuals aged 65 and older. This demographic is more likely to require cancer treatment, contributing to higher projected utilization rates for the CyberKnife. Based on data from the American Cancer Society, the incidence of cancer in Missouri is expected to remain high, with approximately 37,000 new cases projected annually. This supports the assumption that demand for CyberKnife treatments will continue to rise.

The center collaborates with local healthcare providers, including oncologists and surgeons, who refer patients for treatment. As awareness of the benefits of the CyberKnife grows, referral rates are expected to increase. Positive patient outcomes and high satisfaction rates with CyberKnife treatments contribute to increased demand. Mercy Hospital South projects a steady increase in the utilization of the CyberKnife System, ensuring that it remains a critical resource for advanced cancer care in the St. Louis region.

9. Document that consumer needs and preferences have been included in planning this project and describe how consumers had an opportunity to provide input.

When planning new services, Mercy Hospital South incorporates comments from members of the medical staff, patients, area residents and Mercy co-workers. Additionally, the hospital's board of directors includes community leaders who provide input into the services of the hospital.

10. Provide copies of any petitions, letters of support or opposition received.

Letters of support are attached to this application and are included in this section. The letter authors include:

- Jenny Shaffer, MD
- Peter DiPasco, MD, FACS, FSSO
- Mayrol Juarez Klein, MD

No opposition has been received for the acquisition of the linear accelerator. If any letters of opposition are received, they will be forwarded to the CON Program Office.

11. Document that providers of similar health services in the proposed service area have been notified of the application by a public notice in the local newspaper.

A public notice seeking comment on this matter was published in the St. Louis Post Dispatch on 8/25/2024. A copy of the notice is included in Divider II-Attachments.

12. Document that providers of all affected facilities in the proposed service area were addressed letters regarding the application.

Emails regarding the application were sent to affected facilities in the service area. Copies of each email are included in Divider II-Attachments.

	Mercy Hospital South Certificate of Need Application
Attachments	
Divider II	
Proposal Description	



Accuray Incorporated 1240 Deming Way Madison, WI 53717-1954 USA

AMENDMENT ONE TO ACCURAY SYSTEM SALES AGREEMENT

This Amendment One to Accuray System Sales Agreement ("<u>Amendment One</u>") is made effective as of December 8, 2023 ("<u>Effective Date</u>"), by and between **ACCURAY INCORPORATED** ("<u>Accuray</u>"), and **MERCY HOSPITAL ST. LOUIS LOCATED** at 607 S. New Ballas Rd., Suite 1275 St. Louis, Missouri 63141 (the "<u>Customer</u>"), each separately being a "<u>Party</u>" and collectively the "<u>Parties</u>".

WHEREAS, TomoTherapy Incorporated and Customer are parties to the Accuray System Sales Agreement (Contract Number: 04042018JD6-MHSL) dated as of April 27, 2018 (the "Agreement");

WHEREAS, effective as of July 31, 2023, TomoTherapy Incorporated merged with and into its parent company, Accuray Incorporated, with Accuray Incorporated surviving the merger (the "Merger");

WHEREAS, pursuant to the Merger, Accuray Incorporated assumed the Agreement, including all of TomoTherapy Incorporated's rights and obligations thereunder; and

WHEREAS, Accuray Incorporated and Customer want to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual promises contained in this Amendment One, the Parties hereby agree as follows:

1. The Agreement, Site Address on Page 1, which reads as follows:

Mercy Health St. Louis David C Pratt Cancer Center 607 S. New Ballas Rd., Suite 1275 St. Louis, Missouri 63141 USA

shall be replace with the following:

Mercy Hospital South 10010 Kennerly Road St. Louis, Missouri 63128 USA

2. Section A on pages 1,2,3of the Agreement shall be deleted in its entirety and replaced with the following:

A. Quote

All amounts are quoted in US Dollars.

Accuray Deliverables	Quantity	Price	Line Total
CyberKnife® S7™ FIM System	1.00	8,100,000.00	8,100,000.00



ACCURAY

	1		
Accuray Precision® Treatment Planning System Workstation	1.00	210,000.00	210,000.00
Warranty. A 12 month warranty period is included commencing from the date of Acceptance, and shall not exceed 24 months from the delivery of the Accuray Deliverables in this Agreement (including any Accuray Deliverables (Non-Discountable) below), as set forth in the Accuray Terms and Conditions of Sale. Warranty includes all parts and labor as specified in the <i>Warranty</i> Section of the attached Accuray Terms and Conditions of Sale.			Included
New System Training. 20 New System Training Seats are included as set forth in the Accuray Terms and Conditions of Sale.			Included
Rigging and Unloading. Rigging and Unloading costs a as set forth in the Accuray Terms and Conditions of Sale.	Included		
		<u>Subtotal</u>	8,310,000.00
Mercy Health System Discount. Customer shall receive a discount off the Accuray System price if (i) this Agreement is signed and received by Accuray by the Expiration Date and (ii) Accuray receives from Customer the first payment due with this signed Agreement, as set forth in Section B below.			-2,695,000.00
Volume Discount. Customer may be eligible to receive a Volume Discount in accordance with the terms and conditions set forth in the Volume Purchase Agreement. This Volume Discount must be repaid to Accuray under certain circumstances as set forth in the Volume Purchase Agreement.			-3,000,000.00
Multiple System Discount. Accuray agrees to offer Custofor the purchase of multiple Accuray Systems as follows. Multiple System Discount off the Accuray System Subtot (a) this Agreement and any of the following agreeme 04042018JD2-MHSP, 04042018JD4-MHSP, 04042018JI MHSL (together, the "System Agreements") is signed and before the Expiration Date. If Customer is no longer eligidue to inability to timely meet any of the above requirement any of the above System Agreements for any reason, this disto the final payment due by Customer as detailed below, or been received by Accuray, then Customer agrees to refu Accuray within thirty (30) days.	-250,000.00		
Subtotal (after Discount)			2,365,000.00
Accuray Deliverables (Non-Discountable)	Quantity	Price	Line Total
RoboCouch® Patient Positioning System (Flat Top)	1.00	1,010,000.00	1,010,000.00
Non-Discountable Subtotal			1,010,000.00
Third Party Products (Non-Discountable) – Subject to the Third Party Products Note below	Quantity	Price	Line Total
	0.00	0.00	0.00

AMENDMENT STD 3.1.21A





Third Party Products Total	0.00
<u>TOTAL DUE</u> (Subtotal (after Discount) + Non-Discountable Subtotal + Third Party Products Total) (excluding taxes)	* * / * / 111111 11111

Configuration Note. Please refer to **Attachment A** for a description of the base Accuray System as well as Additional Options available for purchase.

- 2. Section B.1 shall be deleted in its entirety and replaced with the following:
 - 1. Payment Terms.
 - 1.1. The payment terms below are based on the Total Due above in Section A, excluding any applicable taxes. *All amounts are quoted in the currency mentioned in Section A above.*

90% due five (5) days prior to shipment

Remaining balance due upon Acceptance.

- 3. The following shall be added as a new Section B.4 to the Agreement:
 - 4. Anticipated delivery. The anticipated delivery date is December 2024, after which point Accuray reserves the right to cancel this Agreement. Execution of a new agreement by Customer may require revision of the Purchase Price of the Accuray Deliverable at thencurrent rates. One-time extension of the anticipated delivery date, up to six (6) months from original anticipated delivery date, may be granted if Customer provides a timely written request and an additional non-refundable deposit in advance and Accuray consents to such request. In the case of cancellation, Customer forfeits any payments made.
- 4. Attachment A of the Agreement shall be deleted in its entirety and replaced with the new Attachment A attached hereto as Exhibit A.
- 5. All provisions of the Agreement, except as expressly modified by this Amendment One, will remain in full force and effect and are hereby ratified and reaffirmed. In the case of direct conflict or conflict by reason of interpretation between any provision of this Amendment One and the Agreement, this Amendment One shall control and supersede the terms of the Agreement.
- 6. This Amendment One in combination with the Agreement contains the entire agreement of the Parties hereto with respect to the subject matter hereof, and supersedes all prior understandings, representations and warranties, written and oral.

SIGNATURE PAGE FOLLOWS



Page 4 of 7

IN WITNESS WHEREOF, the Parties have caused this Amendment One to be executed as of the Effective Date by their duly authorized representatives. The Parties acknowledge and agree that this Amendment One does not become effective until it has been signed by all Parties indicated below.

ACCURAY INCORPORATED

Ву:	By:
Print Name:	Print Name:
Title:	Title:
D .	Date:

AMENDMENT ONE TO ACCURAY SYSTEM SALES AGREEMENT



ACCURAY

Exhibit A

See attached.

ACCURAY

Attachment A

Accuray Base CyberKnife Configuration and Additional Options

A. CyberKnife® S7TM FIM System

\$8,100,000.00

1. Robotic Treatment Delivery System

- 1.1. Image-Guidance System
 - 1.1.1. Diagnostic X-ray sources
 - 1.1.2. Two (2) In-floor amorphous silicon X-ray detectors
- 1.2. Linear Accelerator (LINAC)
- 1.3. Robotic Manipulator
- 1.4. Fixed Collimators
 - 1.4.1. Twelve (12) fixed collimators: 5mm 60mm
- 1.5. Standard Treatment Couch
- 1.6. Treatment Delivery Control Console
- 1.7. IrisTM Variable Aperture Collimator
- 1.8. InCise[™] Multileaf Collimator
- 1.9. Xchange® Robotic Collimator Changer

2. Standard Tracking Capabilities and Indication Packages

- 2.1. Synchrony® Fiducial TrackingTM
- 2.2. CNS Package
 - 2.2.1. Synchrony® Skull Tracking™
 - 2.2.2. Synchrony® Spine Tracking SupineTM
- 2.3. Prostate Package
 - 2.3.1. Synchrony® Fiducial Tracking TM with InTempo TM Imaging
- 2.4. Spine Prone + Lung Package
 - 2.4.1. Synchrony® Spine Tracking ProneTM with Respiratory Modeling
 - 2.4.2. Lung Optimized Treatment
 - 2.4.3. Synchrony® Lung Tracking™ with Respiratory Modeling
 - 2.4.4. Synchrony® Fiducial Tracking™ with Respiratory Modeling

3. Accuray PrecisionTM Treatment Planning System Packages*

- 3.1. Two (2) Precision® Treatment Planning System Workstations
 - 3.1.1. Multi-modality Imaging Fusion (Rigid)
 - 3.1.2. Multi-modality Deformable Image Registration
 - 3.1.3. Standard Contouring Tools
 - 3.1.4. Sequential Optimization
 - 3.1.5. Monte Carlo Dose Calculation
 - 3.1.6. Multiple Session Support
 - 3.1.7. Plan Review and Approval
 - 3.1.8. Plan Comparison and Summation
 - 3.1.9. Plan Transfer Support
 - 3.1.10 VOLOTM Optimization
 - 3.1.11 Multiple Brain Metastases Grouping
 - 3.1.12 AC/PC Oblique Slicing
 - 3.1.13 Gradient and Conformality Index
- 3.2. Head & Neck AutoSegmentationTM
- 3.3. Brain AutoSegmentationTM
- 3.4. Male Pelvis AutoSegmentationTM





3.5. PreciseRTXTM

*Accuray has partnered with RaySearch Laboratories. Treatment planning for CyberKnife® Systems can now be performed on RayStation Planning Systems, in addition to Accuray Precision. For more information, please contact your Accuray representative. Note that all of these products are subject to regulatory approval in your location and may not be available for sale in all territories.

4. <u>iDMS® Data Management Systems</u>

- 4.1. iDMS® Primary Server (Note: One is included with the first Accuray Treatment Delivery System at customer site)
 - 4.1.1. DICOM Import (Image, RTStructure)
 - 4.1.2. DICOM Export (CT, RTStructure, RTDose, RTPlan)
 - 4.1.3. Image Review and Import
 - 4.1.4. System Administration Data Tools
 - 4.1.5. Patient Data Archive/Restore
 - 4.1.6. Integrated Multi-System Patient/Treatment Management
 - 4.1.7. iLink Remote Diagnostic System
- 4.2. OIS ConnectTM
- 4.3. iDMS® Report Administration
- 4.4. iDMS® Storage Vault
- 4.5. TxViewTM

5. General Accessories & Peripherals

5.1 Printer

6. Specialty Color System Option (1071093-000)

6.1 Note: PN 1071093-000 does not need to be ordered if the customer wants the standard Base Blue color. If a Specialty

Color is to be ordered, select from the list below.

- 6.1.1 Specialty Color Neutral (Grey)
- 6.1.2 Specialty Color Breast Pink
- 6.1.3 Specialty Color Prostate Blue



Ms. Alison Dorge Program Coordinator Certificate of Need, DHSS 920 Wildwood Drive Jefferson City, MO 65109

To whom it may concern:

I am writing to formally request a Certificate of Need for the acquisition and installation of a CyberKnife at Mercy Hospital South's Sindelar Cancer Center. As a radiation oncologist, I am confident that this advanced technology will significantly enhance our ability to provide state-of-the-art cancer treatment to the South St. Louis community.

The CyberKnife system will complement our existing Accuray Radixact Tomotherapy unit and Elekta Versa HD, allowing us to offer a broader range of precise and effective treatment options. The addition of the CyberKnife will enable us to treat patients with complex tumors that are difficult to reach with traditional methods, thereby improving patient outcomes and expanding our treatment capabilities.

Our current equipment has served us well, but the CyberKnife's unique capabilities, including its ability to deliver high doses of radiation with sub-millimeter accuracy, will allow us to treat a wider variety of cancers with greater precision and fewer side effects. This will not only improve the quality of care we provide but also attract more patients to our facility, thereby supporting the growth of our oncology program.

The South St. Louis community has a growing need for advanced cancer treatment options, and the addition of the CyberKnife will help us meet this demand. By expanding our technological capabilities, we will be able to offer cutting-edge treatments that are currently unavailable in our region, ensuring that our patients receive the best possible care close to home.

We are committed to providing the highest standard of care to our patients and believe that the CyberKnife Linear Accelerator is essential to achieving this goal. We respectfully request your approval for this Certificate of Need, which will allow us to continue to grow and serve our community effectively.

Thank you for your consideration.

Shift

Sincerely,

Jenny Shaffer, MD

Radiation Oncologist



Ms. Alison Dorge Program Coordinator Certificate of Need, DHSS 920 Wildwood Drive Jefferson City, MO 65109

To whom it may concern:

I am writing to you as the Regional Service Line Chair for Oncology in Mercy's East Community to request a Certificate of Need for the acquisition and installation of a CyberKnife system at Mercy Hospital South's Sindelar Cancer Center. This advanced technology will be the third linear accelerator at our facility, complementing our existing Elekta Versa HD and Accuray Radixact systems.

The Sindelar Cancer Center is committed to providing the highest quality of care to our patients. The addition of the CyberKnife system will significantly enhance our capabilities in delivering precise, non-invasive treatment options for various types of cancer. This technology is particularly beneficial for patients with tumors that are difficult to treat with traditional methods, offering them a new hope for effective treatment.

Our current linear accelerators, the Elekta Versa HD and Accuray Radixact, have been instrumental in providing state-of-the-art radiation therapy. However, the increasing number of patients and the complexity of cases we handle necessitate the expansion of our treatment options. The CyberKnife system will allow us to offer stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) with unparalleled accuracy, minimizing damage to surrounding healthy tissues and improving patient outcomes.

The addition of the CyberKnife system aligns with our mission to provide comprehensive cancer care and supports our goal of being a leader in oncology services in the region. We anticipate that this new technology will not only improve the quality of care for our patients but also attract more patients seeking advanced treatment options, thereby enhancing the overall healthcare landscape in our community.

We respectfully request your approval for this Certificate of Need, which will enable us to continue our commitment to excellence in cancer care. Thank you for considering our application.

Sincerely,

Dr. Peter DiPasco, MD, FACS, FSSO

Regional Service Line Chair – Oncology East Community

Surgical Oncology & Endocrine Surgery



Ms. Alison Dorge Program Coordinator Certificate of Need, DHSS 920 Wildwood Drive Jefferson City, MO 65109

To whom it may concern:

As the Chief Medical Officer of Mercy Hospital South, I am writing to formally request the acquisition of a CyberKnife system for our Sindelar Cancer Center. This advanced technology will serve as our third linear accelerator, complementing our existing Elekta Versa HD and Accuray Radixact systems.

The Sindelar Cancer Center is an APEx accredited facility, recognized for its excellence in radiation oncology. Despite our current capabilities, the addition of the CyberKnife system is essential to further enhance our treatment options and improve patient outcomes. The CyberKnife offers unparalleled precision in targeting tumors, which is crucial for treating complex cases that are not amenable to traditional radiation therapy.

The addition of the CyberKnife will enable us to broaden our treatment capabilities, especially for patients with inoperable or surgically challenging tumors. It will also enhance the precision and effectiveness of our radiation therapies, leading to fewer side effects and a better quality of life for our patients.

Given the increasing incidence of cancer and the need for cutting-edge treatment modalities, the addition of the CyberKnife system is a necessary investment in the future of our cancer care services. We are committed to providing the highest standard of care to our patients, and the CyberKnife will play a pivotal role in achieving this goal.

Thank you for considering this request. We look forward to your favorable response.

Sincerely,

Dr. Mayrol Juarez Klein, MD Chief Medical Officer

Mercy Hospital South

Customer Ad Proof

220-60003625 **MERCY/CONROY MEDIA-LEGALS**

Order Nbr 136347

Publication	Post - Dispatch		
Contact	MERCY/CONROY MEDIA-LEGALS	PO Number	Betsy Thompson
Address 1	2015 SPRING ROAD STE 235	Rate	 Legal
Address 2		Order Price	565.16
City St Zip	OAK BROOK IL 60523	Amount Paid	0.00
Phone	6309207800	Amount Due	565.16
Fax			
Section	Legals	Start/End Dates	08/25/2024 - 08/25/2024
SubSection		Insertions	1
Category	9000 Public Notices	Size	16
Ad Key	136347-1	Salesperson(s)	Tanya Lemons 1023
Keywords	Public Notice Mercy Hospital S	Taken By	Tanya Lemons
Notes			

Ad Proof

Scheduled for publish one time Sunday [Tanya Lemons 8/19/2024 9:56:05 AM]

Public Notice

Mercy Hospital South will file a certificate of need application with the Missouri Health Facilities Review Committee, requesting approval to acquire a linear accelerator. The system will be located at Mercy Hospital South at 10010 Kennerly Road St. Louis, MO. Anyone with comments or questions about this matter should contact Tyler Sturgeon, CFO for Mercy at 314-525-1000 or tyler.sturgeon@mercy.net

STL\stllemot 1 of 1 8/19/2024 9:56:20 AM



August 23, 2024

Fred R. Mills FACHE Homer G. Phillips Memorial Hospital 1320 N Jefferson Ave St. Louis, MO 63106

Dear Fred Mills,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

The system is manufactured by Accuray. For more information about the system, please see the manufacturer's website at: CyberKnife S7 Launch - Accuray

If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.



August 23, 2024

Tina Garrison DePaul Hospital 3800 Park Ave St. Louis, MO 63110

Dear Tina Garrison.

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

Steven Scott, MPH, FACHE St. Louis University Hospital 1201 S Grand Blvd St. Louis, MO 63104

Dear Steven Scott, MPH, FACHE,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

Steven Scott, MPH, FACHE St. Louis University Hospital South 1755 S Grand Blvd St. Louis, MO 63110

Dear Steven Scott, MPH, FACHE,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

Kyle Grate St. Clare Hospital 1015 Bowles Ave Fenton, MO 63026

Dear Kyle Grate,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

Steven Scott, MPH, FACHE St. Mary's Hospital 6420 Clayton Road St. Louis, MO 63117

Dear Steven Scott, MPH, FACHE,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at <u>tyler.sturgeon@mercy.net</u> or 314-525-1930.



August 23, 2024

Andrew Bagnall, MHA, FACHE St. Luke's Des Peres Hospital 2345 Dougherty Ferry Rd St. Louis, MO 63122

Dear Andrew Bagnall, MHA, FACHE,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

Andrew Bagnall, MHA, FACHE St. Luke's Hospital 2705 Dougherty Ferry Rd #201 St. Louis, MO 63122

Dear Andrew Bagnall, MHA, FACHE,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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August 23, 2024

John Lynch, MD Barnes Jewish Hospital 4901 Forest Park Ave St. Louis, MO 63108

Dear Dr. John Lynch,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.



August 23, 2024

Angelleen Peters-Lewis, PhD, RN, FAAN Barnes Jewish West County Hospital 12634 Olive Blvd St. Louis, MO 63141

Dear Angelleen Peters-Lewis, PhD, RN, FAAN,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

The system is manufactured by Accuray. For more information about the system, please see the manufacturer's website at: CyberKnife S7 Launch - Accuray

If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.



August 23, 2024

Hossain Marandi, MD, MBA, FACHE 1465 S Grand Blvd St. Louis, MO 63104

Dear Dr. Hossain Marandi,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

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If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.



August 23, 2024

Ann Abad 3844 Lindbergh Blvd St. Louis, MO 63127

Dear Ann Abad,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

The system is manufactured by Accuray. For more information about the system, please see the manufacturer's website at: CyberKnife S7 Launch - Accuray

If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.



August 23, 2024

Trish Lollo One Children's Place St. Louis, MO 63110

Dear Trish Lollo,

Good afternoon,

Mercy Hospital South is applying to the Missouri Health Facilities Review Committee for a Cyber Knife linear accelerator. A new regulation specifies that hospitals in the area be notified directly.

The system is manufactured by Accuray. For more information about the system, please see the manufacturer's website at: CyberKnife S7 Launch - Accuray

If you have questions or concerns about our implementation of the project, please contact Tyler Sturgeon at tyler.sturgeon@mercy.net or 314-525-1930.

	Mercy Hospital South Certificate of Need Application
Divider III	
Service Specific	
Criteria & Standards	S

DIVIDER III – Service Specific Criteria and Standards:

1. For new units, address the minimum annual utilization standard for the proposed geographic service area.

Not applicable

2. For any new unit where specific utilization standards are not listed, provide documentation to justify the new unit.

Not applicable

3. For additional units, document compliance with the optimal utilization standard, and if not achieved, provide documentation to justify the additional unit.

For additional linear accelerator units, the optimal annual utilization is 6,000 treatments. Mercy has exceeded this volume at Mercy Hospital South in the most recent three full fiscal years, as follows:

Historical Utilization (2 units)				
FY22	20,579			
FY23	20,775			
FY24	21,821			

- 4. For evolving technology address the following:
 - Medical effects as described and documented in published scientific literature;
 - The degree to which the objectives of the technology have been met in practice;
 - Any side effects, contraindications or environmental exposures;
 - The relationships, if any, to existing preventive, diagnostic, therapeutic or management technologies and the effects on the existing technologies;
 - Food and Drug Administration approval;
 - The need methodology used by this proposal in order to assess efficacy and cost impact of the proposal;
 - The degree of partnership, if any, with other institutions for joint use and financing.

Not applicable

	Mercy Hospital South Certificate of Need Application
Divider IV	
Financial Feasibility	

DIVIDER IV – Financial Feasibility Review Criteria and Standards

1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.

Ernst & Young LLP conducted the external audit for Mercy Health, the applicant's parent organization, for fiscal year ending June 30, 2023. The consolidated balance sheet (included in Divider IV – Attachments) verifies the ability of the applicant to fund this project. Audited financial statements for fiscal year 2024 have not been issued at this time.

The applicant has sufficient unrestricted funds to fund this project.

2. Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) FULL years beyond project completion.

Mercy's fiscal year runs from July 1-June 30 each year.

The Service-Specific Revenues and Expenses Form for the projected periods are included in Divider IV – Attachments.

3. Document how patient charges were derived.

The applicant does not expect this project to impact patient charges directly. Charges are based on market conditions and are the result of payment policy established by Medicare and Medicaid, as well as negotiations with commercial payers. Such charges are not directly affected by new equipment or replacements.

4. Document responsiveness to the needs of the medically indigent.

Mercy Hospital South is a Catholic, not-for-profit organization. Collection policies are sensitive to those patients who do not have the ability to meet full financial obligations. Mercy Hospital South provides financial assistance to patients based on need as determined by the Federal Poverty Guidelines. Patients who qualify for financial assistance will not be required to pay more than amounts normally billed to individuals who have insurance. The amount billed is a discounted percentage of the amount due based on federal poverty guidelines.

In fiscal year 2024, Mercy Hospital South provided \$10.1 million in unreimbursed charity care (based on the cost of providing services) and \$20.9 million in unreimbursed care for Medicaid patients.

	Mercy Hospital South Certificate of Need Application
Attachments	
Divider IV Financial Feasibility Review Criteria	and Standards
Tandardan Tandard Tandard	

Mercy Health

Consolidated Balance Sheets

(In Thousands)

	June 30			
		2023		2022
Assets				
Current assets:				
Cash and cash equivalents	\$	529,638	\$	766,187
Accounts receivable, net		830,562		847,319
Inventories		133,162		131,315
Short-term investments		46,883		46,421
Other current assets		198,850		131,922
Total current assets		1,739,095		1,923,164
Investments		3,392,083		3,366,968
Property and equipment, net		3,455,079		3,362,960
Other assets		895,036		886,149
Total assets	\$	9,481,293	\$	9,539,241
Liabilities and net assets Current liabilities: Current maturities of long-term obligations Accounts payable	\$	29,558 445,718	\$	32,709 459,449
Accrued payroll and related liabilities		502,586		499,880
Accrued liabilities and other Total current liabilities		440,021		628,273
Insurance reserves and other liabilities		1,417,883		1,620,311 650,023
Pension liabilities		669,710 231,654		269,048
Long-term obligations, less current maturities		2,173,361		2,198,157
Total liabilities		4,492,608		4,737,539
Total hadilities		4,472,000		1,737,337
Net assets:				
Without donor restrictions		4,806,304		4,626,359
With donor restrictions		182,381		175,343
Total net assets		4,988,685		4,801,702
Total liabilities and net assets	\$	9,481,293	\$	9,539,241

See accompanying notes.

SERVICE-SPECIFIC REVENUES AND EXPENSES

Project Title: Acquire Linear Accelerator **Project #:** 6140 HS

Historical Financial Data for Latest Three Full Years plus Projections Through Three Full Years Beyond Project Completion

Use an individual form for each affected service with a		Year	
sufficient number of copies of this form to cover entire peri and fill in the years in the appropriate blanks.	FY2022	FY2023	FY2024
Amount of Utilization:*	20,579	20,775	21,821
Revenue:			
Average Charge**	\$2,246	\$2,767	\$3,783
Gross Revenue	\$46,220,434	\$57,484,425	\$82,548,843
Revenue Deductions	35,929,913	45,941,727	70,141,492
Operating Revenue	10,290,521	11,542,698	12,407,351
Other Revenue	0	0	0
TOTAL REVENUE	\$10,290,521	\$11,542,698	\$12,407,351
Expenses:			
Direct Expenses			
Salaries	691,892	852,506	935,280
Fees			
Supplies	78,695	83,512	76,674
Other	604,177	465,220	422,423
TOTAL DIRECT	\$1,374,764	\$1,401,237	\$1,434,377
Indirect Expenses			
Depreciation	1,044,167	1,138,149	1,117,504
Interest*** Rent/Lease			
Overhead****	560,270	508,875	545,702
TOTAL INDIRECT	\$1,604,437	\$1,647,024	\$1,663,207
TOTAL EXPENSES	\$2,979,201	\$3,048,261	\$3,097,583
NET INCOME (LOSS):	\$7,311,320	\$8,494,437	\$9,309,767

^{*}Utilization will be measured in "patient days" for licensed beds, "procedures" for equipment, or other appropriate units of measure specific to the service affected.

^{**}Indicate how the average charge/procedure was calculated.

^{***}Only on long term debt, not construction.

^{****}Indicate how overhead was calculated.

SERVICE-SPECIFIC REVENUES AND EXPENSES

Project Title: Acquire Linear Accelerator Project #: 6140 HS

Historical Financial Data for Latest Three Full Years plus Projections Through Three Full Years Beyond Project Completion

Use an individual form for each affected service with a		Year	
sufficient number of copies of this form to cover entire peri and fill in the years in the appropriate blanks.	Year 1	Year 2	Year 3
Amount of Utilization:*	24,615	25,347	26,121
Revenue:			
Average Charge**	\$3,981	\$4,093	\$4,208
Gross Revenue	\$97,992,315	\$103,745,271	\$109,917,168
Revenue Deductions	82,954,468	<u>87,837,671</u>	93,077,739
Operating Revenue	15,037,847	15,907,600	16,839,429
Other Revenue			
TOTAL REVENUE	\$15,037,847	\$15,907,600	\$16,839,429
Expenses:			
Direct Expenses			
Salaries	1,142,151	1,213,543	1,290,310
Fees			
Supplies	97,020	104,161	111,893
Other	957,048	1,015,074	1,077,453
TOTAL DIRECT	\$2,196,219	\$2,332,778	\$2,479,655
Indirect Expenses			
Depreciation	1,599,647	1,599,647	1,599,647
Interest***			
Rent/Lease	((2.057	702.026	
Overhead****	662,957	702,026	743,923
TOTAL INDIRECT	\$2,262,604	\$2,301,673	\$2,343,570
TOTAL EXPENSES	\$4,458,823	\$4,634,451	\$4,823,226
NET INCOME (LOSS):	\$10,579,024	\$11,273,150	\$12,016,203

^{*}Utilization will be measured in "patient days" for licensed beds, "procedures" for equipment, or other appropriate units of measure specific to the service affected.

^{**}Indicate how the average charge/procedure was calculated.

^{***}Only on long term debt, not construction.

^{****}Indicate how overhead was calculated.